FDA STREAMLINING GOOD MANUFACTURING PRACTICES FOR HEARING AIDS WORKSHOP

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A P P E A R A N C E S

(Continued)

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C O N T E N T S

P R O C E E D I N G S

DR. EYDELMAN: Good morning, everybody. My name is Malvina Eydelman. I'm the Division Director in the Office of Device Evaluation at the Center for Devices and Radiological Health in the Division of Ophthalmic and Ear, Nose, and Throat Devices.

I would like to welcome all of you to Streamlining Good Manufacturing Processes -- Practices for Hearing Aids Workshop. We're delighted to see so many hearing impaired consumers, consumer advocacy groups, hearing healthcare providers, professional societies, and industry members joining us today.

For today's workshop the interpreting services staff will be providing real time captioning as well as sign language interpreters. Ms. Angela Stark, who will stand up, can address any press questions.

Everybody should already have a copy of the agenda. But if you didn't receive one, I believe there are extras at the registration table

outside this room.

Now, I'm greatly honored to introduce FDA's Commissioner Dr. Robert Califf who will be providing opening remarks for our workshop today.

Prior to joining FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of Duke Clinical Research Institute.

A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, healthcare quality and clinical research Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science with more than 1,200 publications in the peer review literature.

Dr. Califf has served on the Institute of Medicine committees that recommended Medicare coverage of clinical trials and the removal of ephedra from the market as well as on IOM committee on identifying and preventing medication

errors and the IOM Health Sciences Policy Board. He has served as a member of the FDA Cardiorenal Advisory Panel and FDA's Sciences Board Subcommittee on Science and Technology.

While at Duke, Dr. Califf led major initiatives aimed at proving methods and infrastructures for clinical research including the Clinical Trials Transformation Initiative.

He also served as a principal investigator for Duke's Clinical and Translational Science Award and the NIH Healthcare Systems Research Collaborator Coordinating Center.

Dr. Califf joined us in February of 2015 as the FDA's deputy commissioner for medical products and tobacco. In February of 2016, Dr. Califf was appointed as our commissioner. We're truly delighted to have Dr. Califf give us our opening remarks.

DR. CALIFF: Thanks so much. And I'll be brief because you have really important work to do today.

I do want to welcome all the attendees

to this important workshop. And I was especially pleased to see the broad representation in those who signed up from across the public spectrum -- industry, hearing healthcare providers and their professional societies, consumer advocates for the hearing impaired, and most importantly individuals with hearing impairment.

One of the really important aspects of the FDA which is much deeper than I thought it was before I came is direct interaction with people who are affected by health problems and issues and dealing directly with them.

In addition to the invited attendees who are here, we've received an enormous response from the public with over 200 people registered for this workshop. And we'll hear from many of you during the public session today.

I think some people who are not used to coming to FDA don't realize where White Oak is so we're sort of used to people filtering in as the morning goes through and they get used to Washington traffic.

The issue of hearing loss is one that permeates society. Nearly 38 million American adults, about 15 percent, report some form of hearing loss. And that only increases with age. For those between 65 and 74 it rises to 25 percent and of those 75 and older fully 50 percent have some type of significant hearing loss.

But another factor makes these numbers even more problematic. That's because while there are a number of technologies that exist today to help compensate for hearing impairment, only a small percentage of individuals who could benefit from the use of a hearing aid have ever worn one.

Fewer than one in three adults age 70 and older with hearing loss have ever used one. And for those between ages 20 and 69, only about 16 percent of the people that could benefit from wearing hearing aids have ever used them.

A number of factors have been offered to explain this gap. These include high costs, the perceived stigma of wearing a device, and the performance expectations of these devices.

The FDA is very interested in the affordability, accessibility, effectiveness, and the use of hearing aids by hearing-impaired consumers. We strongly support the application of new technologies to encourage advancement in hearing and technology -- in hearing aid technology as well as better access to hearing aids and other listening devices that will help meet the challenge of a large and growing population with hearing impairment.

That's why we've convened this public workshop. It provides an invaluable opportunity for us to hear from key stakeholders on how we can most effectively regulate hearing aids to promote accessibility and affordability while encouraging innovation in this area.

We want your help and input to explore these issues, develop solutions, eliminate barriers to access, and spur development of new devices that compensate for impaired hearing.

You'll have the chance to discuss a range of hearing devices as well as how these

devices interact with the current regulatory system. We want to discuss ways to accelerate innovation while still enabling and ensuring quality design, manufacturing, and appropriate use of hearing aids.

In some ways as we were talking with PCAST about their initial report this balance of things that I just mentioned is at the crux of almost everything the FDA is dealing with in today's society.

As most of you who are here today understand, this can be a complicated area of regulation. That's due in part to developments in the field as a result of technological advances that may not have been matched by changes in Federal law.

In general, most hearing aids today are regulated as low-risk medical devices. And as such, they are generally exempt from premarket review and clearance by the FDA prior to marketing the device.

But because they're intended for use in

the diagnosis, treatment, or mitigation of a disease or condition they are nonetheless required by law to comply with basic regulatory controls for medical devices.

These requirements involve principles such as good manufacturing practices, the prohibition of adulteration and misbranding, and registration and listing requirements.

Congress established these requirements for medical devices back in 1976. I don't know if you'll be going over the history here, but it was fascinating for me to hear about how all this came about from door-to-door sales of hearing devices that basically didn't work. It's sort of a lesson about the whole history of the FDA with responses to negative societal events generally leading to more authority for the FDA. And then the issue is how do you get that authority in the right place so that technology can advance but people are protected?

Congress gave FDA the responsibility to ensure these requirements at met and that the

devices in this area are safe and effective. But as you know since the Federal policy was enacted 40 years ago and especially over the last decade or so we've seen an amazing number of technology developments in this field and in the general fields that would pertain to hearing aids.

This has included many devices that are not intended for treating or mitigating hearing loss, but are designed for other types of listening situations. And these devices fall outside the regulations for hearing aids.

The proliferation and the number and types of these products has been accompanied by a growing confusion over what these products are designed for and what they are being used for or promoted as doing. FDA has taken a number of actions to address this confusion and clarify what the regulations require. In 2009, the agency published a final guidance that defined and described the regulatory differences between hearing aids and personal sound application products or PSAPs.

I'm sure most of you saw the New York Times article today that went over some of this I thought in a very interesting way.

And in 2013 FDA published a draft revision of this final guidance. And we're recently reopened a public comment period on this draft guidance.

Along with the developments in the field has come increased study of the issue. For instance, the IOM is conducting a study that's examining regulatory and other barriers to hearing aid use. I'm pleased that FDA's a co-sponsor of this study and I know you'll hear more about it today.

Additionally, last October PCAST issued a report that recommended possible modifications of the regulation of hearing aids. Their conclusion was based on the opportunity to enhance the pace of innovation and lower costs while also improving the capability, convenience, and use of assistive hearing devices.

We're pleased that PCAST has taken an

interest in hearing aid use in adults. This does get the direct attention of the President so it tends to get priority. And we're also actively reviewing the report and each of its recommendations.

Today's meeting is an opportunity to discuss all these developments and many other issues related to this topic. We're here to listen and we're open to considering alternative regulatory approaches that may reduce costs and foster innovation and ultimately benefit the public.

Our goal is to ensure that our regulations and policies are clear, up to date, and understood. Only then can they best protect the American public while fostering innovation in this critical area of public health.

And I'm a little bit excited today because in my new job I sort of go from meeting to meeting always trying to stay caught up. But a couple of things have opened up today so hopefully I'll be able to drop in and listen to the

proceedings because I can assure you when Eric Lander called and said we have this PCAST report it got our attention. And we had some fascinating discussions about what's at stake here both for hearing aids in the public, but also questions about how we regulate in areas that are moving very fast technologically where many people are involved.

So we look forward to your engagement in this issue and look forward to a great day today. Thank you.

DR. EYDELMAN: Thank you very much, Dr. Califf, for your insightful remarks.

Now I would like to introduce Dr. Michael McQuade. Dr. McQuade received his Ph.D., masters, and bachelor's degrees in physics from Carnegie Mellon University.

Currently he's the senior vice president for science and technology at United Technologies Corporation where his responsibilities include providing strategic oversight and guidance for research, engineering, and development activities

throughout business units of the corporation and at the United Technologies Research Center.

Prior to joining United Technologies Corporation in 2006, Dr. McQuade served as vice president of 3Ms medical division. Throughout his career Dr. McQuade held several other senior positions with technology development and business oversight.

He has broad experience managing basic technology development in the conversion of early stage research into business growth.

Currently Dr. McQuade serves as a member of the Secretary of Energy Advisory Board and the President's Council of Advisor's on Science and Technology.

We're delighted that he can join us today to discuss the opportunity for improvement in hearing technologies for the aging population which was the focus of the PCAST report issued in October 2015. Dr. McQuade?

DR. MCQUADE: Thank you very much. Good morning, everybody. Despite the bio, I just want to clarify. I'm here on behalf of PCAST to give

an opportunity to talk about the report. Dr. Califf, thank you very much for helping us be a part of the dialog here today.

And while the topic today is around good manufacturing practices and potential ways to streamline that, I do want to set just the context by giving you an overview of the PCAST report in general, how we got to where we ended up today.

So the PCAST report is part -- was part of a broader examination that PCAST had underway and has since released a report relative to aging and technologies and technologies to assist the aging population here in the United States.

In the process of that report we recognized a timely opportunity to support older adults with mild to moderate hearing loss. And I want to be very clear that our comments reflect specifically around age-related mild to moderate hearing loss.

Children, adults with severe hearing loss, those with red flag conditions, et cetera are decidedly outside the scope of the study that

we conducted.

Untreated hearing loss in adults, in older Americans is a substantial problem as we have said before. The causes are many and they may be complex; however, we believe and the report lays out that the focus on a few specific actions taken by the U.S. Government to broadly increase innovation and broadly increase access to hearing aids for adults with mild to moderate age-related hearing loss are appropriate.

As is usual with PCAST, we work out studies by groups that are formed by members of PCAST. The two lead members of PCAST were our co-chairs, Chris Cassel who at the time from the National Quality Forum, and Ed Penhoet.

Additional PCAST members on the report included Jim Gates, Susan Graham, myself, Craig Mundie, Chad Mirkin, and Bill Press, a number of others. And as is usual we assembled working group members from outside PCAST to participate in the study.

I'm also joined here by Dr. Ashley

Predith who is now the executive director of PCAST and was a big part of the study that we went -- had -- had underway.

So urgent need to improve hearing loss, to improve hearing. I'll set the numbers and you've heard some of these before. 30 million Americans have difficulty hearing now. It's associated with additional -- additional consequences, social isolation, dementia, falls, depression, other conditions that are consequent with hearing loss.

It is obviously of growing importance for us as the population ages. Nearly half of the people over the age of 60 have some hearing loss now. And as the number of older Americans rise that number will rise to as many as 80-million plus by 2040. So it's an issue that it is timely to address.

And most striking of all few adults with hearing loss actually use hearing aids and that really is something at the heart of the PCAST report.

We identified cost, among other issues, as a major barrier to the use of hearing technologies. On average, hearing aids in the United States at the level -- at the retail level are about a $2,400 expense per hearing aid. And the conditions that we focused on were conditions where mild to moderate age-related hearing loss were bilateral conditions. So on order of magnitude, $5,000 per person.

Most people pay out of pocket. As has been said, Medicare and many insurance do not yet cover hearing aids for a lot of reasons. A lot of reasons related all the way back to the 1990- -- 1966 Medicare Amendments.

You will see in the report that we did not take on the issue of reimbursement. This issue has been proposed and addressed numerous times over the decades. Probably nine -- at least nine different times legislation has been proposed to change that. That is still not the case.

And it is our belief that innovation has not significantly yet reduced the cost of hearing

aids. Features that we find in consumer electronics that may be applicable to mild to moderate hearing loss and enhanced hearing function features like blue tooth connection, features like connection to smart phone applications, connections to additional processing offline from hearing aids typically are seen as added value incremental cost items. They can range between 500 and $1,000 per hearing aid for the additional cost to a consumer to access those premium features.

PCAST then believes that there are possibilities to mirror the innovation that occurs in the consumer electronics industry to bring that kind of innovation to bear on hearing -- on hearing aid technology and to accomplish wider application of technology into the hearing aid -- into the hearing aid marketplace.

Other barriers include the fact that it can be difficult for consumers to shop for value in hearing aids. In many cases related to the bundling of hearing -- of the whole hearing aid

process from a certified examination through to a certified dispenser, complex and varied state regulations, and in many cases significant restrictions to online shopping.

It is also evident that while 20 percent of hearing aid dispensers carry only one brand that would argue that 80 percent are carrying more than one brand. The data indicates that for those who carry more than one brand of hearing aid at dispensing 75 to 80 percent of the dispensers dispense only one brand. So the issue of bundling and connectivity between dispensation is an issue that we think is important to take a look at.

There is also associated with hearing aids significant -- can be significant social stigma and limited consumer awareness which we believe is also a barrier.

And a significant -- another significant issue that we address is the lack of engagement by healthcare providers in the process of differentiating between significant hearing loss and mild to -- mild to moderate hearing loss.

So conclusions and scope of our study. We believe the problem or the challenge is ripe for change as we speak. New technology is advancing rapidly and we believe, as I said before, that a few key actions are important to gain momentum for those needed changes.

The conclusions, as I said, untreated hearing loss of tens of millions of Americans is a greater challenge than the small -- real but small risk of unusual medical conditions. And we believe that -- we believe that this is a problem that an opportunity exists to increase access for better, cheaper technology.

And we use as a model the reading glass model just to be very -- very clear in the way we went about our analysis. There is not a one-to-one correspondence, but there are analogies here that make sense.

Medical exams to identify underlying severe conditions are laudable. We believe that should be balanced against easing the process for adults with mild to moderate hearing loss related

to age-related cause.

The example that we quote in the report is that -- is that, sorry, acoustic neuroma -- the condition of acoustic neuroma for which one might be very concerned about a process that reduces the attachment to the medical community. It's about a 1 in 90,000 occurrence in adults with hearing loss and so we have a regulatory framework around hearing loss that tries to protect against that.

Conversely, 3.4 percent of adults suffer from glaucoma and yet we allow adults to receive eyeglasses over the counter. So there's an analogy in here that while not perfect, is relevant to the conversation that we have in place.

Dr. Califf also mentioned that inherent in this conversation are the issue around PSAPs, personal sound amplification devices. To be clear, we speak about both of those in the report and we do draw a distinction between those. Although the PSAP industry can be used as a model for technology development and so we want to be

sure that that -- that that is taken into account.

So our recommendations, our conclusion -- and I'm going to quote just for clarity. Americans would be better served if non-surgical air conduction devices intended to address bilateral gradual onset milder to moderate age-related hearing loss were available over the counter. So lots of caveats in there as to where we believe the opportunity for advancement occurs.

OTC sale is appropriate in our opinion when consumers are able to self-diagnose, self-limit, and self-manage a disease or condition. So that's what drives our recommendations.

Our goals were to reduce cost to consumers, to increase the number of people who use hearing technology, and to stimulate innovation and technology development in the industry.

So our first recommendation in the report is that the FDA should designate a distinct basic hearing category for non-surgical air conduction hearing aids intended to address normal

bilateral gradual onset mild to moderate age-related devices. And that in so doing it should adopt specific and distinct rules for those devices.

I want to be very clear. We have said it numerous times, but I want to be very clear in public here we do not favor weakening FDA's overall regulatory framework in any way, shape, or form beyond the specific recommendations around hearing aids in this report.

So the FDA should approve this class of hearing aids for over-the-counter sales without requirement for consultation and credentialed -- with a credentialed dispenser.

It should approve for OTC sales both in store and online tests appropriate to the self-fitting and adjustment of those devices by the end user. Such treatments and tests meet FDA requirements for OTC products which are that consumers should be able to self-diagnose and self- treat.

The FDA should exempt this class of

hearing aids from QSR regulations in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer electronics industry developed by an appropriate third party organization and approved by the FDA.

Similar action should be taken with respect to hearing tests used to dispense and fit these Class I hearing devices.

We did this recommendation on the fundamental belief that a failure in the design and/or manufacturing and performance of such a device does not pose a health risk. And that the market forces in the consumer electronics industry coupled with the increased volume would be sufficient to protect consumer interests and the health of consumers in this process. So that's our first recommendation.

Our second recommendation is related to PSAPs. We're recommending that the FDA withdraw its latest draft guidance from la- -- from November of 2013 and that PSAPs should be broadly

defined as devices for discretionary consumer use that are intended to augment, improve, or extend the sense of hearing in individuals.

At issue here is that the 2009 guidance as augmented by 2013 issues stricter la- -- stricter requirements on labeling forbidding what can be truthful claims and capabilities on the concern that those claims can be interpreted to represent correction of hearing loss.

So while we understand what the FDA guidance is trying to approve, it runs the risk in our opinion that people who legitimately without any form of hearing loss, without any form of disease or underlying conse- -- underlying condition would not be able to buy PSAPs because of the added guidance. And we believe that is not a necessary or wise step.

Our third recommendation is that in analogy to the eyeglass rule that the FTC should require audiologists and hearing aid dispensers who perform standard diagnostic hearing aid tests -- hearing tests and hearing aid fittings to -- to

provide customer with a copy of their audiogram and the programmable audio profile at no cost to the consumer and in a form that can be readily transported and used by other dispensers and hearing aid vendors.

And, again, an analogy to the eyeglass rule that the availability of hearing tests and fitting should not be preconditioned on any agreement to purchase goods and services of any kind from the provider of the test. So unbundling the distribution and dispensation -- and dispensing from the audio exam.

And then finally our fourth recommendation again to the FTC in analogy to the contact lens rule is that should define a pro- -- so the FTC should define a process by which patients may authorize hearing aid vendors both in state or out of state to obtain a copy of their hearing test results and programmable profile from any audiologist or hearing aid dispenser who performed such a test. And it should require the testers furnish those results at no additional

cost.

While the FTC, in our opinion, has the authority to issue new regulations of this sort, action can be accelerated and strengthened and legislative action. So we urge the administration to work with Congress to initiate bipartisan legislation to instruct the FTC to issue the rulings for hearings aids and PSAPs similar to eyeglass and contact lens rules.

Okay. As it relates to the QSR and quality systems, we believe that changes in regulation can stimulate innovation and technical advances while maintaining critical product quality and recordkeeping.

The electronics industry experiences very fast-paced product cycle and rapid improvements in technology. The actual or conceived -- perceived burden of regulation can slow or present innovation. And in our opinion innovation needs to occur at a higher speed -- higher pace in the hearing aid -- in the hearing aid marketplace and that innovation is spurred by

new entrants.

That does not imply that those in the market today are not innovation, but it does imply that adding -- adding and reducing -- reducing the burden and adding new entrants into the market will, in our opinion, stimulate innovation.

Substantial traditional compliance practices with standards for product quality and recordkeeping appropriate for consumer electronics will apply to this marketplace.

An oversight to match the situation we believe is the appropriate response. Not to eliminate oversight, not to eliminate certain requirements for appropriate recordkeeping, et cetera, but to use the industry that is best in position to accomplish the innovation necessary to achieve the goals of added access and added innovation. We believe that an appropriate FDA-approved third-party organization can act as the interface to accomplish this.

So finally in summary, it's a large cost and large risks for untreated hearing loss in the

United States. Major barriers exist from hearing aid costs and limited ability to shop for best value. And we believe that a few key actions in Federal regulations can accelerate the needed changes to improve innovation, to bring new technology, to lower cost, and ultimately to improve access to those Americans who are subject to age- related mild to moderate gradual onset hearing loss.

Thank you very much.

DR. EYDELMAN: Thank you very much for such a clear summary of PCAST recommendations.

Now I would like to introduce Ms. Ellen Flannery. Ms. Flannery is a member of the National Academies of Science, Engineering, and Medicine Committee on Accessible and Affordable Hearing Healthcare for Adults.

She's also a partner in the law firm of Covington and Burling based in Washington, D.C. Her practice provides regulatory advice to medical device manufacturers regarding FDA's premarket and post-market requirements.

We're very happy to have Ms. Flannery provide us with the update on the ongoing Institute of Medicine study regarding hearing aids.

MS. FLANNERY: Thank you very much. It's very nice to be here today. I am presenting as a member of the National Academies of Sciences, Engineering, and Medicine Committee on Accessible and Affordable Hearing Healthcare for Adults.

And there may be some confusion by some people because everybody knows us as the Institute of Medicine Committee. And the Institute of Medicine has undergone a rebranding and has now become or will be known as the National Academies of Sciences, Engineering, and Medicine. So I just wanted everybody to be aware of that.

I also wanted to say that while my law practice does involve regulatory advice to medical device companies, during my tenure on the committee I have recused myself from any work for hearing aid companies or with regarding to hearing aids.

What I'd like to do today is to give you an overview of the academies, talk about the types of activities undertaken by the academies, describe generally the consensus study process, and then more specifically talk about the process and timeline for the study of our committee on Accessible and Affordable Healthcare -- Hearing Healthcare for Adults.

The National Academy of Science's charter was in 1863. And President Lincoln signed the charter to form the National Academy of Sciences to investigate, examine, experiment, and report upon any subject of science or art.

So the National Academy of Sciences has now expanded to include engineering and medicine and has a long history of service in these disciplines serving the public with regard to its various reports and recommendations.

Although it is chartered by the United States Government, the National Academies of Sciences, Engineering, and Medicine is independent and is an independent non-profit. It is not part

of the Federal Government.

The National Academies undertakes two general types of activities. One is consensus studies such as the study on Accessible and Affordable Hearing Healthcare. The other is to convene workshops and other activities.

And, for example, they convened in January 2014 a workshop on hearing loss and healthy aging. And this is the cover for the report of the workshop summary.

So the consensus study process generally includes first defining the scope of the study; second, committee selection and approval which is a very extensive process; the third is bias and conflict of interest discussions which include various discussions with the staff of the National Academies and then there are additional discussions within the committee where we all discuss each other's experiences and work.

Third -- the next thing is that there are committee meetings. And the committee meetings include public workshops, public

participation and presentations. The committee takes all of this input, drafts the report and recommendations.

This is a carefully crafted process to assure that there is widespread public participation and consideration of a broad range of ideas.

After the report is drafted it is sent out for external review. And the external reviewers provide comments that the committee members and staff then respond to in finalizing the report. The external review helps to strengthen and to clarify various aspects of the report.

There's then a public release by the National Academies and a dissemination of the report to interested parties. But after -- both during and after the release of the report the committee's deliberations remain confidential indefinitely.

So let me address now our consensus study. We had a number of sponsors for this study.

They are listed here in alphabetical order including the Centers for Disease Control and Prevention, Department of Defense, Department of Veteran's Affairs, the Food and Drug Administration, the Hearing Loss Association of America, the National Institute on Aging, and the National Institute on Deafness and other Communication Disorders.

The committee is given a statement of task to which we must adhere. And the statement of task was for the committee to address how to improve accessibility to and affordability of hearing healthcare for adults. We did not address surgical devices and related services nor did we address pharmaceutical products.

Let me go through the specifics of the statement of task which will be addressed in the committee's report.

First was contextual background. We were asked to provide a contextual background addressing the importance of hearing to individual and societal health, productivity, and engagement.

We were asked to look at issues such as isolation, social connectivity and well-being, and economic productivity.

We were asked to address Federal regulations of hearing aid dispensing including the current FDA regulations. So we were looking at the current Federal regulations including the requirement for a medical evaluation by a licensed physician or the alternative signed waiver of this requirement prior to the dispensing of a hearing aid to promptly identify treatable medical conditions that cause hearing loss. This is part of the current FDA requirements.

We were asked within this question to look at three specific questions -- do the current regulations provide a clinically meaningful benefit to adults with hearing loss, does the benefit outweigh any current barriers to accessibility or affordability, and what should be required in the Federal regulatory paradigm for dispensing hearing aids?

We were asked to look at solutions. So

we were asked to provide recommendations aimed both at solutions that are implementable in the short term and those that might require a longer term time frame for implementation.

We were asked to look at the strength of the evidence for various findings. And where robust evidence was lacking or absent we were encouraged to make recommendations for further study based on sound scientific reasoning in the current healthcare environment.

The Academies appointed a 17-member committee. And the members has expertise in hearing healthcare services, audiology, otology, hearing loss advocacy, primary care, geriatrics, health economics, technology policy, law, and epidemiology. So we had a broad range of experiences on our committee.

With regard to our specific committee activities the committee gathered information from the scientific literature, reviewed information submitted by members of the public, and reviewed submissions by various organizations and agencies.

The committee held workshops and public meetings where we received presentations by the study sponsors who I'd listed before, by patients, healthcare providers, industry, researchers, and numerous others. We received both public presentations at the meetings and we also received written comments from members of the public.

At the public sessions the speakers provided their expertise on a variety of topics that were relevant to the statement of task. The committee met several times. We drafted the report, we've drafted the recommendations. We've sent the report out for external review. And now what is pending is the finalization of the report and the release and dissemination.

The typical National Academies report will have 8 to 12 recommendations. The recommendations can be aimed at the Government, non-profits, industry, healthcare professionals, the healthcare system, academia, the research community, the public, and many others.

And the National Academies direction is

that the report's recommendations must be based on evidence. And the recommendations are that, they are recommendations. They are not mandates to anyone.

The study timeline was that we began with our first meeting in April 2015. We had meetings in June, September, and November including the public workshops and presentations. This year we met again in the January/February time frame. We've been working on the report review and response. And the aim is to release the report to the public in early June. And from that point on the National Academies will be working on disseminating the report.

So I want to thank everybody. I hope that when our report does come out that you'll give it careful attention. And we look forward to hearing from you. Thank you.

DR. EYDELMAN: Thank you very much. Now we will proceed to FDA's presentations outlining FDA's current hearing aid regulations.

Dr. Nandkumar who is a branch chief for

ear, nose, and throat devices in the Office of Device Evaluation and Ms. Booth, who is a consumer safety officer in the Office of Compliance, will be providing the presentations.

Nandu?

DR. NANDKUMAR: Good morning. We have in the audience today hearing aid users for whom hearing devices are so important for maintaining a healthy and product lifestyle. We also have representatives of consumer advocacy groups, industrial representatives, representatives of hearing healthcare professional associations, and representatives from the Institute of Medicine and PCAST. Welcome to all of you.

My name is Nandu Nandkumar and I am the branch chief of ENT devices in the Office of Device Evaluation in the Center for Devices and Radiological Health.

We are excited about the enthusiastic response to this workshop over the past several months and we look forward to hearing from everyone during the various sessions today

regarding how we can potentially modify or improve the existing FDA regulations to promote accessibility, affordability and use of hearing aids by the hearing impaired population.

To that end we have sought to minimize the length of the FDA presentations and to allow maximum time for the attendees to present their views and to participate in the question and answer sessions.

I'll begin this morning by providing a brief overview of the FDA regulatory approach to hearing aids and Ms. Shanika Booth from the Office of Compliance will then provide an overview of the good manufacturing practices or GMP regulations that currently apply to hearing aids.

My presentation will cover the regulatory definition of medical devices and specifically hearing aids. I'll say a few words about personal sound amplification products, or PSAPs, given the widespread interest in using these products, but especially by the hearing impaired.

I'll then describe how we classify hearing aids in a risk based classification of medical devices as well as the general regulatory requirements for hearing aids based on their classification.

And next I'll discuss two device specific regulations for hearing aids regarding labeling and conditions for sale.

Per section 201 of the Food, Drug, and Cosmetic Act a medical device is defined as a device intended to diagnose, cure, mitigate, treat, or prevent a disease or condition or is intended to affect the structure or function of the body and does not achieve its intended use through chemical action or metabolism.

Before we get to the regulations that govern hearing aids, I'd like to briefly talk about personal sound amplification products, or PSAPs, from the standpoint of FDA regulations.

There is no formal regulatory definition for PSAPs. Although a working definition we have used in the 2009 FDA guidance on PSAPs and hearing

aids is that PSAPs are intended to amplify environmental sound for non-hearing impaired consumers for use in a variety of listening conditions. For example, hunting, bird watching, listening to lectures and conversations from a distance.

As such, PSAPs do not meet the definition of a medical device because they're not mitigating or treating a disease or condition and therefore are not subject to FDA medical device regulation.

However, PSAPs are subject to the Radiation Control for Health and Safety Act of 1968 that apply to all radiation emitting electronic products including those that emit sound vibration such as sound amplification equipment. These include regulations that govern the defects, failures, repair and replacement.

FDA understands that based on today's technological advances the technological differences between PSAPs and hearing aids are shrinking and are in some cases non-existent.

From the current FDA perspective the differences between the PSAPs and hearing aids is one of intended use. Historically there have always been products intended to amplify sound for recreational and other activities for the normal hearing consumer.

And FDA's 2009 guidance and the draft 2013 guidance were meant to clarify the difference between PSAPs and hearing aids as one of intended use. FDA's regulations do not prevent a consumer with normal hearing or hearing impairment from buying any product or device they choose.

The regulations and guidance documents are meant for the manufacturer and FDA staff to clarify our current thinking regarding the intended use distinction between PSAPs and hearing aids and to provide guidance to the manufacturers regarding labeling of hearing aids versus PSAPs.

We acknowledge PCAST's recommendation regarding the draft to 2013 guidance document and we wish to reiterate that the public comment period for the 2013 draft guidance was reopened

and will remain open until May 6th, 2016.

Under the hearing air regulation 21 CFR 801.420, a hearing aid is defined as any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing. As you can see, this definition broadly encompasses any wearable technology with the intended use of aiding hearing loss.

Also per regulation 21 CFR 874.3300, a hearing aid is a wearable sound amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air conduction hearing aid and the bone conduction hearing aid, but excludes the group hearing aid or auditory trainer master hearing aid and tinnitus maskers. In the rest of my presentation, we will mostly focus on air conduction hearing aids.

Next I'll present how hearing aids are regulated. Rather than a one-size fits all approach, the medical device amendments to the Food, Drug, and Cosmetic Act in 1976 created a

tiered risk-based classification in which the regulatory requirements of any specific device type depend on the level of risk associate with the use of the device.

Without getting into a full description of this scheme, the message that I want to get across is that the basic air conduction hearing aid as a device type is regulated at the lowest risk level, that is Class I, and it only needs to meet general regulatory controls.

So what are these general controls? Here's the summary of the general controls that all Class I devices including air conduction hearing aids must meet. There is a prohibition of adulterated and misbranded devices which in very basic terms means that a device must be what it claims to be and that the labeling must be truthful and accurate and not false and misleading.

Manufacturers must also comply with good manufacturing practices or GMPs, which again Ms. Booth will describe in the next presentation.

They must register their manufacturing facilities with the FDA and list the types of devices they make.

There are certain recordkeeping and reporting requirements include adverse reporting to the FDA when appropriate. There are certain provisions regarding repair, replacement, and refund for devices that pose an unreasonable health risk.

And finally there's a requirement for a premarket application or 510(k) to the FDA prior to going to market. Although for most Class I devices including hearing aids these have been exempted from the 510(k)'s requirement.

So a new manufacturer of an air conduction hearing aid would usually not need to submit any application to the FDA before going to market. They will only need to comply with the other general controls listed on the slide.

As an additional note on hearing aid regulations I wanted to add that wireless hearing aids are defined as air conduction hearing aids

that incorporate wireless technology in the programming or use. And are classified as Class II, but exempt from 510(k) submission to the FDA prior to marketing.

These regulations involve special controls in addition to general controls regarding their design, testing, and labeling of the wireless technology.

Bone conduction hearing aids are regulated as Class II and these require a 510(k) application to the FDA prior to market.

FDA also created additional regulations back in 1977 which were felt to be necessary to ensure safe and effective use of hearing aids. There are two of these regulations. One regarding device labeling and the second regulating the conditions for sale of hearing aids.

These two regulations were the direct result of senate hearings in 1976 which concluded that the hearing healthcare delivery system at that time was not working and directed that FDA should create regulations to

restrict the sale of hearing aids to patients who have undergone a medical evaluation to rule out treatable causes of hearing loss.

The first regulation concerning device labeling requires specific elements to be used in the user instructional brochure including instructions for use. It also includes realistic expectations for performance of the device and so on.

There must be a section entitled "Important notice for Prospective Hearing Aid Users" which emphasizes the importance of medical evaluation before getting hearing aids.

The user brochure must contain certain technical performance data that the hearing aid dispenser can use to select and fit a hearing aid to an individual patient per the ANSI Standard S3.22.

And finally there must be a section called warning for hearing aid dispensers which outlines certain so-called red flag signs and symptoms for which the hearing aid dispenser

should refer a patient to a licensed physician, preferably an ear specialist since these findings indicate a possible medical condition requiring treatment.

My next slide lists the red flag signs and symptoms that that are listed in the user instructional brochure which should prompt a hearing aid dispenser to refer a patient to an ear specialist for further evaluation.

Of note, some of these red flag conditions can be assessed by the patients, themselves, such as presence of pain or dizziness or drainage from the ear. Whereas the others require examination or testing by a hearing healthcare professional such as audiometric findings or examination of the ear canal and eardrum.

The second regulation outlines the conditions under which hearing aids may be sold and dispensed to a patient. Specifically it requires that the patient have had a medical evaluation by a licensed physician

within the preceding six months again to identify medical causes of the hearing loss that may require treatment.

However, an adult patient greater than 18 years of age can actually waive this requirement for a physician evaluation as long as they sign a statement that they understand that the waiver is not in their best health interest. The dispenser must also keep records of these medical evaluations or waivers for a period of three years.

Finally I would like to summarize the regulatory requirements of air conduction hearing aids. As you recall, the regulatory requirements for a basic air conduction hearing aid would include general controls that apply to all Class I devices that we discussed earlier. And like most Class I devices, hearing aids are usually exempt from any premarket submission to the FDA.

Secondly, there's a labeling regulation that outlines what must be in the user instructional brochure for the device.

And finally we have a conditions for sale regulation that includes the requirement of a medical evaluation within six months of sale of the device, but allows a waiver of this requirement in adults.

Wireless hearing aids are Class II and they're exempt usually from 510(k) notification to the FDA. In addition to general controls, the requirements for wireless hearing aids include special controls for the wireless technology and regulations for labeling and conditions for sale.

This concludes my presentation and we'll now hear from Ms. Shanika Booth who will discuss in more detail the good manufacturing practice regulations that apply to hearing aids.

MS. BOOTH: Good morning, everyone. My name is Shanika Booth. I am a consumer safety officer in the Division of Manufacturing and Quality in the Office of Compliance here at CDRH.

My part of the presentation is going to focus on our current regulatory approach with regard to the reporting requirements specifically

of adverse events and the quality system regulation cited under general controls. In addition, I'll present some information gathered on where our hearing aids are coming from as well as some adverse event information.

As Nandu previously mentioned, Class I 510(k) exempt medical devices like the air conduction hearing aids are subject to what are known as general controls. Part of these controls include the requirement to maintain records and report adverse events as well as compliance with the device man- -- good manufacturing practices or GMPs.

Currently there are two important reporting requirements to which hearing aid manufacturers must comply. They are the medical device reporting requirements under 21 CFR 803 and the corrections and removals requirements under 21 CFR Part 806.

Medical device reports or MDRs can be both mandatory or considered mandatory and voluntary. They are considered mandatory as

manufacturers, importers, and user device facilities are required to adhere to the requirements under part 803. They are also considered involuntary as anyone can submit an MDR report such as a patient, a user, family member.

The requirements under corrections and removals are actually the reporting of an involuntary -- excuse me, reporting of an involuntary removal of a correction or correction of a device that poses a risk to health or it's a device in which the manufacturer has determined to be adulterated or misbranded.

Corrections and removals are effective methods to correct or remove any FDA regulated product from the marketplace.

21CFR Part 7, specifically part -- subpart C, provides guidance for manufacturers on policy, procedures, and industry responsibilities as they relate to corrections and removals.

Reporting requirements allow the FDA to monitor the safety of medical devices and to identify potential problems. It also allows the

FDA to assess the effectiveness of a correction or removal as well as to learn more about how marketed devices perform through the reporting.

The good manufacturing practices or GMPs for devices were first authorized by the Food, Drug, and Cosmetic Act under section 502(f). However, the FDA identified the lack of design controls as a major reason or cause for device recalls.

So in 1990 as part of the Safe Medical Devices Act the FDA was given the authority to add preproduction design requirements to the device GMP regulation.

The current quality system regulation became effective in 1997 and it applies to manufacturers of finished devices who intend to market those devices commercial.

Design controls as we know it are part of the current quality system regulation and they apply to all Class III and Class II medical devices and certain Class I devices.

The quality system regulation provides a minimum requirement or framework so to speak to ensure finished devices are safe and effective. I'll mention one of my favorite parts of the quality system regulation is the preamble to it. It not only includes comments that were received prior to the final rule of the current quality system regulation, but also provides insight in the intent of the quality system regulation.

21 CFR Part 820 requires the development of a quality management system. And this quality management system should be equivalent to the risk presented by the device, the complexity of the device, and its manufacturing process as well as the size and complexity of the manufacturer.

The quality system regulation ranges from 820.20 of management responsibility through 820.250 statistical rationale.

An easy way to break up the quality system regulation is to divide it into subparts of management control, design and development

control, product and process controls, as well as corrective and preventive action or CPA.

The design control requirement under 820.30 is the process of controlling and monitoring design activities for a medical device to ensure that specified design requirements are met.

Design controls again apply to all Class III and Class II medical devices. Most Class I devices are exempt from the design control requirements; however, when Class I devices such as the air conduction hearing aids or their accessories utilize software or contain programmable technology design controls must be applied.

Devices subject to design controls are considered to require close control of the design process to ensure that the device performs as intended given the consequences that could occur if the designs are flaw or if the device would fail to meet its intended use. There are,

however, some exemptions to the quality system regulation.

Again, most Class I devices are exempt from the design control requirement under 21 CFR 820.30. In addition to hearing aids, there are a few Class I devices which are subject to design controls.

The update provides a list of these devices under 21 CFR 820.30(a). And those devices include devices such as surgeons' gloves or protective restraints.

The FDA also recognizes that there are certain Class I devices that are exempt from the quality system regulation. For example, if these devices are not labeled or otherwise represented as sterile. GMP requirement does not, however, exempt manufacturers of finished devices from complaint files under 21 CFR 820.198 or the general requirements concerning records under 21 CFR 820.180 as well as the other requirements stated under general controls.

Currently hearing aids are subject to

the quality system regulation as well as the design control requirements within it. There are criteria, however, that exist that comes out of the 1982 Federal Register where if these particular criteria are met the FDA will consider exempting manufacturers of Class I devices from the GMP regulation. The criteria are:

If the FDA has determined based on adequate information about current practices in the manufacturer of the device and about user experience with the device that the application of the GMP requirement is unlikely to improve the safety and effectiveness of the device.

If the FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectible for use either through visual examination or by the user or routine testing before use such as testing of a clinical laboratory reagent against positive and negative controls.

Additionally, if the FDA has determined that any defect in the device that is not readily

detectable will not result in a device failure that would have an adverse effect on the patient or other user.

Again, manufacturers whose Class I devices are exempt from the GMP regulation must still comply with complaint handling and general recordkeeping.

In the current regulatory environment we are able to monitor safety and effectiveness of devices already on the market as well as the effectiveness of corrections and removals. We are also able to identify or monitor exactly what's coming into the U.S. through imports.

And here is a snapshot -- five year snapshot from 2011 to 2015 of hearing aid entry lines. Now I want to note that an entry line does not relate to a specific number of devices or items. They can actually represent 1 or 1,000 devices. And in this case over the last five years there have been over 356,000 hearing aid entries declared at imports.

The increase that you see here actually

follows the increasing trend observed that more and more manufacturers are outsourcing functions such as contract manufacturing.

Now while there were over 300,000 hearing aid entries declared, the number of entries detained or refused entry altogether is relatively low. Devices can be detained or refused entry into the U.S. if there's an appearance of a violation of the Food, Drug, and Cosmetic Act or from sampling and analysis by an FDA laboratory where the sample has found -- been found to be out of compliance. Entries may also be detained simply for clerical error if the information is incomplete or inaccurate or unclear.

Now while there have been over 300,000 lines declared in imports over the last five years, the number of adverse events has been relatively low. Between 2011 and 2015 there were no corrections and removals reported.

There were a significant amount of MDRs submitted specifically in 2013 that appears to coincide to a significant spike in hearing aid

sales; however, the -- compared to other devices the amount of MDRs is relatively low.

So in summary, hearing aids are subject to general controls which include reporting issues of device malfunction and where risk or serious injury or death exist as well as the adherence to the quality system regulation which provides the basic framework for the design manufacturer and distribution of safe and effective devices.

It's also important to note that manufacturers whose devices are exempt from the GMP regulation must still meet the requirements for complaint handling and recordkeeping. Thank you.

DR. EYDELMAN: Thank you very much. This concludes FDA presentation. We will now take 20- minute break. I want to point out that there's caffeine outside for those of you who need it.

We will start promptly at 10. Thank you.

(Whereupon, a brief recess was taken at

9:37 a.m., and resumed at 10:00 a.m.)

DR. EYDELMAN: We will now proceed with the open public speaker session. During the open public session public attendees are given an opportunity to present data, information, or views relevant to the workshop agenda.

FDA places great importance in the open public session process. The insights and comments provided can help the agency in our consideration of the issues before us.

That said, in many instances and from many topics there will be a variety of opinions. One of the goals today is for this open public session to be conducted in a fair and open way where every participant is listened to carefully and treated with dignity, courtesy, and respect.

To date, FDA has received 19 comments submitted to the docket. Please note that the docket will remain open till May 19th to allow individuals to post additional comments for our consideration.

FDA received 27 requests to speak prior

to the final date published in the Federal Register. 24 of these individuals have confirmed their attendance today. We have allocated three hours to hear from the public speakers and, therefore, each speaker will be given seven minutes to summarize their viewpoints.

In order to ensure that each speaker is cognizant of their speaking time, we will provide colored lights to visually aid them. When each talk begins the light will be green. It will turn yellow when the speaker has one minute left and then red when the speaker reaches the seven-minute mark.

At this time I would like -- I would like to ask the first 12 public speakers as currently displayed on the screen to please come up and take a seat at this table in front of the room.

Please note that the sequence of public speakers today was assigned based on the order in which they registered for this workshop.

When your name is called please step up

to the podium and state your name and any organization you are representing for the record. After you have finished presenting please return to your original seat in the audience.

Once again, we want to emphasize that each speaker should limit their comments to seven minutes so as to provide ample opportunity for everyone to contribute.

Now I will like to ask Mr. Ronquillo to please step up to the podium.

DR. RONQUILLO: Hello. Thank you very much for the opportunity to speak today. My name is Dr. Jay Ronquillo and I'm speaking on behalf of the National Center for Health Research.

I'm a physician who trained at Massachusetts General Hospital. I have two engineering degrees from Cornell, a master of public health from Harvard, and a master's in biomedical informatics from Harvard Medical School. These are the perspectives I bring with me today.

Our research center analyzes scientific

and medical data and provides objective health information to patients, providers, and policymakers. We do not accept funding from the drug or medical device industry and I have no conflicts of interest.

Age related hearing loss is an important condition affecting many patients. Hearing aids and related technologies are capable of improving the quality of life for many of these men and women. Increasing access and availability to these technologies will be critical, but their quality, safety, and effectiveness must also be a priority.

The PCAST report recommends creating a separate category for basic hearing aids. Over-the- counter sale of these hearing aids would likely increase the number of people who use hearing aids; however, there remains several unanswered questions regarding their quality and safety.

Are current hearing aids sufficiently effective for this larger population?

Do people with hearing aid problems know

where and how to report major problems with either safety or effectiveness?

Also how do patients know which products will best meet their specific needs?

Because the FDA currently regulates hearing aids as Class I or Class II devices which require little if any data supporting their safety and effectiveness the answers to these questions are not clear.

Similarly, over-the-counter sale of hearing aids would place the responsibility on patients to self-diagnose, self-treat, and self-monitor their specific type of hearing loss. For patient population often affected by multiple conditions and taking multiple medications or treatments this would place additional burden on patients without keeping manufacturers accountable for device quality and safety.

Under this approach there would also likely be more patients with non-age related hearing loss that would go undiagnosed and untreated. And it would be even less likely that

problems with these hearing devices would be reported or monitored. To avoid harming the public health we urge you to recommend medical or clinical guidance.

In summary, we support the need to improve access to high quality hearing aids and other medical devices for the aging population; however, we are very concerned that there is a heavy focus on increasing the adoption of hearing aids that is not balanced by strong, explicit attention to safety or to devices that work well for the individuals buying them.

We recommend stronger evidence explaining and supporting the safety and effectiveness of devices that impact hearing. Thank you again for the opportunity to speak today and for consideration of our views.

DR. EYDELMAN: Thank you very much. Ms. Parady?

MS. PARADY: Good morning. My name is Alissa Parady. I am the Government affairs director for the International Hearing Society

which is a professional membership association that represents hearing aid dispensing professionals in nearly 40 countries, including hearing aid specialists, audiologists, and physicians.

Personally I am a hearing aid user. I -- my first ENT evaluation revealed sensory neural hearing loss. Second evaluation identified my loss as otosclerosis so I was very glad that I pursued that second opinion. I know many others would perhaps not do so.

IHS has significant concerns with the recommendations put forth by PCAST. My commentary today will relate to PCAST recommendation related to the expanded use of PSAPs by individuals with bilateral age related mild to moderate hearing loss.

First, we'd like to thank the FDA for taking action to reduce consumer confusion and harm by developing the 2013 draft guidance on PSAPs. The 2009 guidance really opened the flood -- flood gate to this class of retailers and as a

result consumer confusion is at an all-time high.

The 2013 guidance is urgently needed because some retailers continue to blur the line of the role of PSAPs and addressing hearing loss. Here are some examples.

One PSAP retailer is using statements on its website: "Studies show even slight hearing problems reduce your earnings potential, increase your chances of dementia, social isolation, and even your likelihood of falling."

Another website sells products called sound amplifier hearing aid alternatives. There website states: "Our hearing amplifier helps improve speech intelligibility and reduces fatigue associated with the inability to hear what you want."

I can't help but think of the times I've sat in briefings listening to experts like those from Better Hearing Institute and Johns Hopkins talk about the ties between hearing loss and falls, earnings, dementia, and cognitive load leading to fatigue.

To boot, the top of the line sound amplifier hearing aid alternative is listed at about $3,800; however, a price reduction takes the actual price down to just $399. Clearly these companies and others like them are targeting people with hearing loss.

The 2013 guidance provides truly needed examples of labeling claims in language that would define the intended use as a medical device such as a description of the types and severity of hearing loss and wording to suggest that the product is an alternative to a hearing aid.

The guidance is helpful in providing illustrative examples which was largely lacking in the 2009 guidance and is necessary to reduce consumer confusion and keep PSAP retailers in line.

To be clear, IHS takes no issue with the sale of PSAPs to normal hearing consumers to provide a hearing boost.

We do take issue with PSAP retailers targeting hearing impaired individuals and

knowingly bypassing Federal and state regulations that ensure appropriate use, safety, and effectiveness.

People experiencing loss for the first time should seek a hearing evaluation with a licensed provider so they know the cause of their loss and options available. Then they are positioned to make an informed decision which may include a hearing aid or if they so choose a PSAP.

Curtis Alcock in the Hearing Review in November explained how nearly impossible it is to self-detect slowly progressing hearing loss. In brief, individuals who self-identify hearing loss are the exception rather than the norm. And it usually means either a perceptible contract has developed or that reduction in hearing has already become severe enough which means that a delay in intervention has already taken place.

And these are the people the ones most likely to adopt hearing aids as a solution under the PCASTs model for which professional evaluation may be the most necessary. So for the FDA to

authorize or promote PSAPs as a solution will undoubtedly do more harm.

The benefit of a professional evaluation and professionally fit hearing aid versus an off-the-shelf PSAP as it relates to the cost differential has been dismissed by many. There is no mechanism for tracking bad outcomes with PSAPs on a large scale I know; however, the incidents of consumers being harmed is real and happens regularly.

I'd like to share a hearing aid specialist experience with two patients in Wisconsin. The first patient was having ongoing trouble with devices he'd purchased online. He believed that they were hearing aids, but they were, in fact, PSAPs.

After much prompting by friends he agreed to see Samantha. He said the devices weren't working and that he had pain in one of his ears. When she looked in his ear she found three tips which had broken off of the device that were lodged in the ear. He had no idea.

When he called the company he bought them from to complain the tip had fallen off they just mailed him new tips. They didn't ask him what happened to them nor did they tell him to go see a physician.

She immediately referred him to a physician and the tips had to be surgically removed. He sustained several infections and incurred significant cost due to the surgery and infections.

She had another person come to see her who had initially started wearing hunter's ears for hunting, but liked them so much that he started wearing them all the time.

After five years he decided it was time for a better solution; however, because the programming of the PSAPs was not appropriate for his loss and despite the fact that his loss was not that bad, his speech understanding had become very poor. So despite attempts to fit him with hearing aids that just wasn't going to be a workable solution for him.

Fortunately these patients don't have under- -- didn't have underlying medical conditions causing the loss, but there are many stories of patients who have gone to see hearing aid specialists who needed that medical referral and often times very quickly to avoid or address a more serious situation.

IHS surveyed its members in 2014 asking how many had seen a patient in their office who had purchased a PSAP who later came to them for assistance. 87 percent had. Of those 87 percent, more than half observed one or more patients with possible medical conditions prompting referral to a physician.

PCAST described a line between PSAPs and hearing aids as having led to a natural experiment. When you consider failed experiments like the Japanese model that makes PSAPs widely available and which has led to terrible adoption and satisfaction rates the U.S. cannot afford to experiment with the American hearing impaired population.

We are not aware of any evidence that loosening the restrictions on PSAPs will improve adoption and outcomes. The evidence points in the exact opposite direction.

The PCAST report states its goals are to make hearing healthcare more affordable and accessible; however, without adoption of the 2013 guidance the atmosphere and confusion -- of confusion and mistrust and unethical behaviors by PSAP retailers targeting our vulnerable older population will only get worse and hearing aid adoption will suffer.

IHS urges the FDA to make final the 2013 guidance. Thank you.

DR. EYDELMAN: Thank you very much. Mr. Jon Schirado, please proceed to the podium.

MR. SCHIRADO: Thank you very much for allowing me the opportunity to speak here this morning. My name is Jon Schirado and I work for Sivantos, Inc., formerly known as Siemens Hearing Instruments. I'm the regulatory affairs manager there and my job here today is to show you a

manufacturer's perspective of the FDA regulations.

There's been much talk about how the big six dominate the hearing aid industry and how the FDA regulations pose a burden that is so high that it inhibits competition.

As shown by a look at the FDA registration database there's actually 96 manufacturers listed in the database for Class I and non-wireless. For Class II wireless there are 44 manufacturers listed. Well beyond the big six that there are claims the industry is limited to.

One of the main deficiencies that I saw in the PCAST report was that it kept talking about Class I air conduction hearing aids. If you look at our industry, 87 and a half percent of the hearing aids sold in 2015 were wireless hearing aids. That's Class II with special controls.

The fact that the recommendations do not address this that 7 out of 8 hearing aids are sold that are wireless or Class II special controls, things that address things like pacemaker compatibility and other wireless issues, in my

mind is a grave deficiency.

In terms of FDA registrations I started working the industry in 1995. In 1998 they removed the 510(k) requirement. So for the last 17 years we have not had to do a 510(k) to put a product on the market. I will show later the FDA is actually much more efficient in registering new devices than Canada, Mexico, our European partners.

Lastly, when I say it's not a burden, but it's actually a benefit. If you look at the import data, and Shanika had a little bit on that, there is a tariff preference for hearing aids that PSAPs do not get. It's actually a 4.9 percent tariff benefit that resulted in $77 million savings to hearing aid manufacturers.

As I mentioned, if you look at -- excuse me -- if you look at the Class I manufacturers that are registered there are 96. 48 are in the U.S. So 50 percent domestic. The other 48 are actually located in 19 different countries. If that's not a good distribution of competition I

don't know what is.

Similar for Class II. Class II has 44 manufacturers registered. Out of that 19, or 43 percent, are in the U.S. 57 percent are in 13 different countries. Once again, quite a distribution for manufacturing.

If you look at why is there a fall off from Class I to Class II? Even though 87 percent of hearing aids are wireless, why are there less than half as many Class II manufacturers?

It's because of technology. If you look at it, the R and D that's required to be established in the industry is very difficult. The FDA requirements are not that much different. There's still a QSR compliance, but what you have is special controls in terms of EMC compatibility, non-ionized and radiation.

As I mentioned, the trend in wireless hearing aid purchased in the U.S. 2014 was 82. It's up another 5 and a half percent in 2015. We need to address the issue of how are Class I wireless hearing aid handled. The fact that we

don't is, to me, a deficiency that needs to be corrected.

The rationale in 2011 for why the FDA decided to regulate wireless hearing aids is clear. It's the potential effects on other medical devices such as pacemakers. You also have the issue of non- ionized and radiation. There was concerns looking at it similar to cell phone radiation. The good thing is for hearing aids much lower battery and power consumption so therefore you don't have the exposure, but it's still something that has to be taken into consideration.

To me the replacement of the FDA special controls and QSR compliance for these Class II devices with voluntary electronic standards unreasonable exposes the public to unsafe and ineffective devices.

When FDA made the change in 2011 they did the study that determined there would not be a significant economic impact on a substantial number of small entities. I recommend we go back

and look at that study and see what its impact was.

When I mentioned that FDA registrations are much easier than our North American counterparts -- to give you an idea it takes 3 to 12 months to register a device in Mexico. Canada takes 3 to 4 weeks. The U.S., I go online, it takes 5 minutes. So in terms of burden it's hard to convince me that it's difficult to register hearing aids in the U.S.

As talked about before, the QSR is harmonized with the ISO standards and also there are several countries now -- you got Japan, Canada, Brazil, and Australia have what's called the MDSAP which means that a regulatory audit can take place by one of the registrars and it'll count for a regulatory audit for the other countries.

As you can see, the harmonization is taking place in more and more countries; therefore, if the U.S. decides to no longer regulate hearing aids we still have other quality

system regulations in other countries.

By the elimination of QSR compliance in the U.S. you're not going to eliminate from other countries. Also the Veteran's Administration and large big box stores actually require ISO 9001 or 1345 compliance in their contracts so you're still going to have that requirement.

Last point on there is that the FDA estimated an average burden of 220 hours for a startup manufacturer marketing a device for the first time. Not a very onerous task.

Getting to the import part, hearing aids and their components are tariff free. What that translates to is, this ties into Shanika's stats, the last 20 years you can see the amount and the increase in the imports of hearing aids and hearing aid components over the last 20 years. It's over a billion dollars. That's where the stat of $77 million in savings comes from.

In actuality there's probably PSAP manufacturers who are registering as hearing aid manufacturers just to bring it in for the tariff.

Thank you very much for the time.

DR. EYDELMAN: Ms. Gail Gudmundsen?

MS. GUDMUNDSEN: Good morning. This is the third time I've addressed FDA. In 2001 Mead Killion and I challenged the outdated hearing aid rule and asked FDA to create and over-the-counter hearing aid. In 2008 we spoke to Director Schultz in the hearing aid working group.

I want to provide context for my remarks. My career as an audiologist spans 42 years. I began dispensing hearing aids in 1978. I worked in two metropolitan hospitals and owned a private practice for over 20 years. I'm a principal of an R and D manufacturing company that develops diagnostic medical devices, hearing protection, and consumer electronics for the ear.

In 2003 I submitted a citizen petition requesting revocation of the requirement for medical evaluation. The fact that a large number of adults signed a waiver makes the regulation essentially meaningless. And the number of medical conditions that might be missed without

this requirement is negligible. The petition was denied.

The Consumer Bill of Rights. In 1962 President John F. Kennedy spoke to Congress and outlines four basic consumer rights. In 1985 the United Nations expanded these to eight rights.

The right to safety is protected by the Consumer Product Safety Commission which works with the industry to develop voluntary product standards.

The right to be informed and the right to consumer education indicate that consumers have a right to be truthfully informed about products so they can make intelligent choices.

Today's consumers are much better informed than those in 1962 and 1985. The Internet makes it possible for consumers and their advocates to acquire knowledge to make informed choices. Ineffective products can return for a return.

Hearing aid regulations in effect since 1977 are out of step with the current healthcare

climate in the U.S. FDA restrictions on labeling of personal sound amplifiers prevent consumers from the right to be informed.

The right to choose gives consumers the right to buy a wide variety of products without concern that businesses have a monopolistic hold on products and services or in pricing. At this time six companies control 98 percent of hearing aid sales.

As long as FDA maintains that hearing loss is a medical condition and hearing aids are medical devices, consumers are deprived of the ability to choose simple solutions to improve their hearing.

Revised definitions are needed. Hearing loss is not a medical condition. Hearing loss is the result of a disease or medical condition. Over 90 percent of adults with hearing loss need no medical treatment. Age related hearing loss and noise induced hearing loss are not medical conditions.

FDA definition notwithstanding, hearing

aids are not used in the diagnosis of a medical condition nor can they cure, mitigate, treat, or prevent a disease that contributes to hearing loss.

Hearing aids do not affect the structure or function of the body. They do not lessen the severity of intensity of hearing impairment. They simplify -- simple amplify sound to compensate for hearing loss. When the hearing aid is removed the hearing loss is still present.

Intended use. It's neither design nor technology that differentiates FDA regulated devices from unregulated personal sound amplifiers, but regular -- rather intended use.

The technology in many personal sound amplifiers is identical to that in hearing aids. Being allowed only to state that personal sound amplifiers are for persons with normal hearing is disingenuous. The FDA forces manufacturers to withhold information from consumers by not informing them how these products can be useful to them. This violates consumer's right to be

informed and the right to education.

Jurisdiction. The 2013 draft guidance stated that manufacturers couldn't -- would not be allowed to describe listening conditions in which PSAPs may be helpful because those situations are also instances in which hearing aids can provide benefit.

That proposed narrower definition would restrict a consumer's right to know they can purchase a personal sound amplifier for any of those situations. FDA has no authority to dictate the environment in which PSAPs are used. The FDA's attempt to control products not within its jurisdiction is clearly overreaching.

The recent announcement to reopen that comment period which closed over two years ago is perplexing. That guidance should be withdrawn.

Call for reform. In 2011 President Obama issued Executive Order 13563 improving regulation and regulatory review. Particularly relevant to the current discussion are sections 2, 4, and 6.

This order charges agencies to modify, streamline, expand, or repeal rules that are outvoted, ineffective, insufficient, or accessibly burdensome. I urge FDA to consider these directives and revise outdated regulations which add unnecessary cost and limit access to hearing help for millions of Americans.

Premium versus basic technology. Not everyone who needs amplification needs advanced hearing aids. Findings from a respected research group indicate that compared to basic technology hearing aids with advanced features do not improve speech understanding except ability or satisfaction with loudness.

Creating over-the-counter category. Killion's 2013 citizen petition called for an over- the-counter classification of -- for hearing aids. His petition was denied. It was 2003. I'm sorry.

In recent PCAST recommendations OTC hearing aids are again proposed. If President Obama follows the recommendation of his council

advisors, FDA would create an over-the-counter hearing aid category exempt from quality system regulation and delegate authority for quality and performance standards to a third party.

FDA has the authority to preempt state requirements so that over-the-counter devices do not have to be sold by licensed dispensers. Labeling should be informative and include appropriate warnings.

For almost two years a working group in the consumer technology industry has taken steps to establish standards for product quality and performance that will meet a classification for over-the-counter hearing devices.

Conclusion. I participated in this narrative for 15 years. I've read letters from professionals, the organizations that represent them, and the industry that sells to them. I've attended meetings held by NIH and the Institute of Medicine and I've spoken directly with members of the President's Council Advisors on Science and Technology.

Moving forward, the simplest short-term solution while we wait for market forces to decide our future is to allow PSAP manufacturers to tell the truth about their products. Companies should be allowed to describe who can benefit from their products and the listening situations in which the products can be effective even if the situations overlap with the functionality of FDA regulated hearing aids. If abuses occur, the Federal Trade Commission can intervene.

Eliminate the requirement for medical examination. Consumers are smarter than we acknowledge. Consumers do not need Government regulations to protect them from devices that will not harm them.

Any long-term solution needs to repeal the 1977 rule and create a new rule that is designed to make it easier for America -- millions of Americans to afford hear- -- afford -- find affordable hearing solutions.

DR. EYDELMAN: Thank you very much. Ms. Janice Lintz?

MS. LINTZ: Hello. My name is Janice Schacter Lintz. I'm the CEO of Hearing Access and Innovations, a consulting firm, and a mother of a 21-year-old child with hearing loss.

The FDA should require generic names for hearing aid features with a rating system. The consumer has no idea what they are purchasing unless there is greater transparency.

It is easy (sic) to purchase computer brands than hearing aids. Trademark propriety names are used for generic -- for features which make it impossible to compare them. Generic names should be required.

Hearing aid buyers are dependent on audiologist dispensers to provide information which prevents a conflict of interest because the dispenser represents a limited number of manufactures, does not have knowledge of all hearing aids on the market. They are presumed to know the aids on the market, but the on- -- the reality is they only dispense a few brands.

The mix they offer is based on

percentage of earnings, incentive prices, delivery schedule, quality, and customer support. Some of these concerns such as percentage of earnings are not in the interest of the consumer.

They may also receive bonuses, equipment based on the volume of hearing aids sold. Many hearing aid companies are providing free equipment, incentives, or perks including trips. This is frowned up on the pharmaceutical indus- -- but yet -- industry, but yet we are still permitting it in this industry.

There's a financial incentive to maximize the likelihood of making a sale. Dispensers make a substantial profit when they sell hearing aids. Critical information that may obstruct the sale such as pros and cons of various features may not be disclosed.

Hearing aid manufacturers also heavily fund either directly or indirectly through advertising many of the hearing loss organizations which interferes with their advocacy which is why many of them are not on the Hill lobbying for

hearing aid coverage.

Consumers can only education themselves with the information that is easily obtainable and understandable, but there is no incentive for manufacturers or vendors to provide it unless they are required to do so.

The FDA can bring greater transparency and accountability to the dispensing of hearing aids by developing a rating system for the various hearing aids and features based on an international ENC standards and by standardizing the names of these features. The availability of this information will enable consumers to become better informed and more satisfied with their purchase.

Standardizing technology -- terminology for hearing aid features will also help consumers to evaluate personal sound amplification products which are flooding the market. These are more affordable. And if generic names for hearing aid features are used, then consumers would be able to compare PSAPs to hearing aids and see what they

are actually receiving. As Sy Sims said, "an educated consumer is out best customer."

It is insincere for HII -- HIA to state the audiologists would know which hearing aid works best even when they are unable to compare one hearing aid to another. The information just doesn't exist.

CA- -- CEA is an industry-lobbying group funded by membership companies. Having sat on the FCC's Consumer Advisory Committee under Chairman Martin for two terms, they're unlikely to do their part without regulation.

These changes made by CEA primarily occurred, in my opinion, when they were mandated by the FCC including adding a captioning chip to television. The same was true for adding a closed captioning button on television remote controls.

The FCC does not have oversight on hearing aids and there will be no regulatory authority to ensure CEA acts in the best interest of customers with hearing loss.

Another example was when hearing aid --

hearing aids needed to become compatible for cell phones and you needed to know the radio frequency immunity numbers.

The FCC required this for cell phones, but the FDA did not require this for hearing aids. The FDA was unwilling to do this. Having one rating without the other was meaningless.

Some of the cell phone companies grudgingly provided the information in teeny print that was hard to find, failed to train their employees, and refused to provide efficient number of attractive models. The information was available, but good luck finding it.

The FDA also refused to mandate the hearing aid manufacturers to provide HAP ratings. It made it impossible to purchase a cell phone for our daughter. At the time no one at the FCC would contact the appropriate person at the FDA and vice versa.

So it was up to me to contact the FDA and I literally did every single day until we finally received voluntary ratings. That is

absolutely ridiculous and absurd. No one should have to work for free to do another person's job.

To close the remaining gaps that the cell phone manufacturers refuse to provide, CTIA, a voluntary membership organization, could not mandate, but merely suggest and the FCC refused to address. So I wrote an article "How to buy a cell phone when you have a hearing loss" that embarrassed all of the companies to provide what they needed to provide. That again seems absurd. The information would not have moved forward without this article and it was simply ridiculous.

I learned through the process in working with other membership organizations that certain large companies have tremendous clout and place unwieldly pressure on membership organizations. The membership organizations could not mandate anything, but only recommend action.

Placing people with hearing loss who have no market force depending on these organizations is untenable. Success is only accomplished when people like me work for free.

That is simply ridiculous and people with hearing loss cannot be dependent on membership organizations or the generosity of people to receive information they so sorely need.

Another example is my 2009 petition before the FDA has gone unanswered. The hearing aid market needs a radical overhaul, clear regulation, and oversight. The hearing aid industry and audiologist stranglehold must be broken.

HIA's report is self-serving and is intended to protect the organization's funders. Other than cochlear implants there aren't alternatives on the -- aren't alternatives. The aftermarket accessories are only that, aftermarket accessory is similar to selling gum at the supermarket checkout stand. Most of them don't work and are relinquished just sitting in a drawer.

The one product that is routinely not recommended is a telecoil despite being mandated in four states. It's $50. It takes time to

explain and therefore it's omitted. It is needed. And the propriety technology should not replace the telecoil.

HIA's discussion of complex algorithms is also insincere. Audiologists are not mathematicians. The hearing aid manufacturers have developed software to calculate the formulas. The audiogram numbers are input into software to determine the hearing aid program. The hearing aids are adjusted based on consumer input after testing the aids. The statement is just utter nonsense.

Greater transparency of features whether they are hearing aids or PSAPs is needed. Consumers need to understand how the hearing fe- -- how the features serve their needs whether they are purchasing a PSAP or hearing aid. Thank you.

DR. EYDELMAN: Thank you very much. Mr. Chase Smith?

MR. SMITH: Hi. My name is Chase Smith and I'm a doctor of audiology student at Northwestern University. And I'm here today to

share the results of my research project entitled PSAPs versus hearing aids on electroacoustic analysis of performance and fitting capabilities.

Oh, change the slides. Sorry.

DR. EYDELMAN: The slide click is coming.

MR. SMITH: Thank you. So just to reiterate, my opinions and the information I'll present today do not represent those of the organizations that I'm affiliated with.

So my study was conducted in the summer of 2015 at Northwestern and it examined the electroacoustic properties of 11 different hearing aids and personal sound amplifiers. And at that time research had really been focused on perceived sound quality differences in the devices, but hadn't looked yet at the appropriateness of fitting these devices to a range of sensory neural hearing losses you might encounter in those with hearing loss.

So my two questions were what were the output of these devices in comparison to a

traditional hearing aid and could these devices be appropriately fit to certain audiometric configurations?

These were the devices I chose for this study. They were split up into two groups -- PSAPs and hearing aids and also low-end devices and high- end devices based on pricing.

So for part one what I looked at was I put each device in a test box and looked at the maximum output of the device, it's ratio of high-frequency output to low-frequency output. It's noise levels of the device, the distortion produced by the device, and its directional benefit.

So for the first part I looked at the maximum output of the device in terms of its low-frequency output to its high-frequency output. A lot of people had suggested that the low-end PSAPs had a lot of low-frequency gain which would be inappropriate for those with a high-frequency hearing loss.

So you can see essentially in this chart

what you're looking at is the greater the value, the greater the low-frequency output in comparison to the high-frequency output. And you can see the greater the number, the worse the performance was.

So you can see at the bottom the three low-end PSAPs had the greatest amount of low-frequency gain in comparison to high-frequency gain. Whereas the traditional hearing aids and the high- end PSAPs had a more balanced ration of high to low- frequency gain.

Just a quick note about maximum output. There's been suggestions that some of these devices produce too much output for people with mild to moderate hearing losses. So this is just the absolute maximum output of the device.

You can see that the high-end hearing aids which were designed for severe to profound hearing losses have similar output at the maximum level to those low-end PSAPs, as well. The Cyber Science and the Whisper being the low-end PSAPs.

You can also see that the high-end PSAPs actually had a lower amount of overall gain than

those devices which would be more appropriate for somebody with a mild to moderate hearing loss, as well.

Next I looked at the equivalent input noise. So this is essentially how much noise the device generates itself when it's in operation in a patient's ear.

Now looking at this you can see once again the higher the value the higher the amount of noise being generated. ANSI standards dictate a value of around 32, 33 dB. And you can see that the noisiest devices in my study were the three low-end PSAPs.

Now the quick note about input noise. For certain hearing losses this isn't relevant because it'll be beneath their thresholds of hearing and they won't notice it. However if you're discussing noise noticed by somebody with a mild to moderate hearing loss this is pretty important if it's a high amount of noise generated.

Next I looked at total harmonic

distortion which surprised me in that there was a relatively low level of distortion in all of these devices. Even the low-end devices had -- were some of the lowest distorted devices. So that's good because a high amount of distortion can distort your target signal and reduce the intelligibility of the incoming signal.

Finally, directionality is something that was really important to me because there is a large body of research suggesting the importance of directional microphones in increasing speech understanding and noise for patients with a hearing loss.

You can see in this really the only devices with a measurable directional benefit were the two traditional hearing aids. The high-end hearing aids as well as one high-end PSAP, the Sound Hog.

You can see that some of the devices do have a directional benefit, as well; however, research by Dr. Killion has suggested that a direction benefit of less than 2 dB would probably

go unnoticed by a majority of people in a noisy situation. So really only three devices in this study had a directional benefit which is important to note because many patients with hearing loss report hearing and noise as one of their chief complaints.

So part two really are measurements. So what this does is essentially each device was put on a mannequin with a probe microphone placed in the ear canal and a speaker placed in front of the mannequin.

Prescriptive targets were generated for ten different audiometric configurations ranging from very mild to profound and from flat to steeply sloping. These are supposed to represent the range of people you would see in the clinic with a high- frequency sensory neural hearing loss due to aging.

Each prescriptive target -- there were nine prescriptive targets for three intensities -- soft, medium, and loud speech. And a target was considered matched if it was within 10 dB of the

target output.

A total score was generated. Essentially all the targets matched out of 27 and each devices was tested ten times per audiogram.

Now, really measurements are really important because research suggests that patients are most satisfied with a device when it's been fit to prescriptive targets appropriately.

So this is the result of that part of the study. So basically a score of 88 percent or better indicates that targets were able to be matched appropriately. 8 out of 9 targets were appropriately matched at each intensity presentation level. So you can see the blue represents those scor- -- those devices that were able to pass for each audiogram.

So a few things to bear in mind with this chart, the top two devices that were able to fit the greatest number of hearing losses were the two high- end hearing aids. You can see right next to that, though, was a low-end hearing aid. The base M2 available online without consultation

of a dispenser or audiologist was able to fit up to a moderately severe hearing loss.

Next from that was the Sound Hog, a high- end PSAP, which is able to fit appropriately up to a moderate degree of hearing loss. And right below that also being able to fit to a moderate degree of hearing loss was the EarMachine, a $1 app on your iPhone.

Something I'd like to point out as well is that the two low-end PSAPs were unable to appropriately match targets for any degree of hearing loss in this study. And another thing I'd like to point out is the MD Hearing Aid Pro, the third from the bottom, a low-end hearing aid was also unable to appropriately fit targets to any of the hearing loss configurations in this study. Which is important because it is FDA regulated as a hearing aid and makes promises on its website that it can fit up to a moderate degree of hearing loss.

The implications for this being that the high-end hearing aids are the most versatile in

their fitting capabilities and can provide the greatest amplification for the greatest range of losses.

Some high-end PSAPs could appropriately fit a patient up to a moderate degree of hearing loss. And FDA approval does not necessarily dictate a quality or appropriateness of a particular device for a particular patient population. Thank you.

DR. EYDELMAN: Thank you very much. Mr. -- Mr. Richard Einhorn?

MR. EINHORN: Thank you. My name is Richard Einhorn. I am a board member of the Hearing Loss Association of America and representing Einhorn Consulting, LLC, which focuses on hearing loss technology issues.

Can everybody hear me? Great.

First I want to express my grateful appreciation to all in the hearing health industry who have provided technology and services that have enabled me to continue to function despite a devastating sudden hearing loss nearly six years

ago.

While everyone I have met is sincere and passionate about helping people with this disabling and often misunderstood condition, it is my view that the low adoption rate of hearing aid technology points to structural issues with the hearing healthcare system that need to be examined especially in the light of a general increased consumerization of healthcare via the use of powerful mobile digital technology such as smartphones, tablets, watches, and computers.

My comments are directed exclusively to the problem of encouraging more people with mild to relative moderate hearing losses to get help sooner. I certainly believe that hearing aids capable of extreme sound levels appropriate for people with severe, profound, or complex hearing losses like myself should be made available only by some kind of medical prescription delivery system such as the current FDA regulations.

The issue today is whether significant changes to the FDA policies regarding GMPs for

hearing aids suitable for mild moderate losses might encourage earlier adoption of hearing technology.

I believe that the simplest solution for consumers is something similar to PCAST recommendation for a class of devices that could be marketed to people with mild to relatively moderate hearing losses and purchased with no hassle over the counter by any consumer who wants them similar to reading glasses.

Obviously users need to be confident that such devices are safe and effective. But as PCAST points out, consumers also need a regulatory structure that encourages a profusion of high quality, innovative hearing technologies that people will not only be able to afford, but will actually use.

It is important for FDA to understand that there is no fine line to be drawn between hearing enhancement and hearing assistance devices. For example, I have here some fairly new hearing tech.

Full disclosure. Two years ago I consulted for this company, but not in this product.

You put this device in your ear and it works right out of the box. But if you want you can download an app that assesses your hearing and applies an algorithm that will personalize the sound.

And here is another device. You also place this one in your ear and it, too, works right out of the box. And if you want you can download the exact same app the other devices uses, assess your hearing in exactly the same way, and have it apply the exact same algorithm to personalize the sound.

These devices are absolutely identical. But this one is called the hearing aid and this one is called a personal sound amplifier product. This one requires the user to sign a waiver if you want to buy it, but this one does not.

Because they are identical, a person with a relatively moderate hearing loss can put

the PSAP in her ear and receive the same benefit as a hearing aid. Likewise, a person with normal hearing can safely use the hearing aid. And because it is identical to the consumer product meets all the safety requirements governing the consumer electronics industry.

FDA presently draws a sharp distinction between hearing aids and over-the-counter devices based on their intended use depending on whether they compensate for hearing loss or to be used by normal hearing people.

By making this distinction, devices that could be of considerable benefit to people with mild to moderate losses cannot be marketed as such. In fact, the intended use of both hearing aids and PSAPs is, of course, identical. They enable people to hear better in specific situations where they could use some hearing enhancement or if you prefer the word assistance.

Many people who would be officially diagnosed with mild to relatively moderate hearing loss if they were tested do not recognize their

condition as medically important and cannot be convinced otherwise. Still there are many situations where hearing technology could help. How can we reach them?

Instead of persuading the unpersuadable, I believe we need a regulatory structure that is based not on the false premise of intended use for technology, but draws a distinction between medically serious hearing losses and those that presently are not.

I believe we need a regulatory structure for easy-to-obtain hearing devices below a maximum power output level equivalent to consumer-level hear- -- earphones that actively encourages their use by people with mild and fairly moderate hearing losses.

The ultimate goal would be to make the use of hearing assistance enhancement technology as normal and as non-stigmatizing as wearing earphones are today. Some devices would be simple, nearly invisible earbuds that essentially amplify the sound. Others would be colorful,

attractive fashion statements that add reverb or special effects for fun. Still others would simply be smartphone apps that could be used with standard earbuds.

Via an inviting, non-medical approach people would be introduced to hearing assistance who don't perceive their level of hearing as any more medically serious than they would if they had mild myopia and needed magnification for reading.

The considerable psychological stima -- stigma that prevents people from getting help would to some extent be mitigated. For example, even students with normal hearing might at a lecture wear in-ear devices to enable them to hear their professor better. Studies suggest this improves hearing and learning.

If over time someone believes they are struggling in more situations than their over-the-counter devices can help with, then a smoother and earlier transition into prescribed devices which would always be available if people want them may occur.

To encourage people to use hearing assistance technology earlier I urge FDA to set up additional meetings with all major stakeholders including the PSAP Standards Committee at the Consumer Technology Association, the Hearing Industry Association, HLAA, the Triple A, the ADA, ASHA, and knowledgeable individuals with all levels of hearing loss to discuss how regulations and guidances for basic hearing aids or PSAPs, whatever name you wish to call them, can be changed so that they can be marketed effectively to the people that need them and be purchased as easily as possible, preferably over the counter, and without a waiver. Thank you very much.

DR. EYDELMAN: Thank you very much. Mr. David Smriga, please?

MR. SMRIGA: Good morning. My name is David Smriga. I am president of AuDNet, Inc., a group purchasing organization for audiologists. And I'm also senior audiology consultant for Audioscan, a hearing aid fitting verification technology manufacturer.

In my view there are two main issues at the core of any future regulatory guid- -- regulatory or guideline deliberations prompted by these proceedings. Getting effective hearing help to more people to positively impact the comorbidities that most now agree are associated with hearing loss, and to lower consumer costs. I will speak to both.

At the May 2015 meeting of the Acoustical Society of America Dr. Anu Sharma from the University of Colorado described some very important physiologic truth. When subjects with mild age- related hearing loss were stimulated visually, unlike subjects with normal hearing, the image on your left whose occipital lobes responded most robustly to visual pattern stimulation as expected, the subjects with mild age-related hearing loss, the image on your right, repeatedly showed brain reorganization in which the traditional hearing portions of the brain, the temporal lobe, had been recruited for processing visual patterns.

So the initial question everyone in this room needs to ask is this: If a patient who has an age-related hearing loss, a patient whose cortical real estate once used to process speech cues is not wired to the visual system, how would you expect that patient to initially react to the sudden and effective reintroduction of those speech cues?

The answer, as most hearing care professionals would readily tell you, is subjective dissonance. A serious clash between what sounds acceptable at the critical moment of new amplification experience and what is actually needed to meaningfully improve the long-term communication effectiveness and, thus, positively impact comorbidities.

This also leads to a second key question. Can a rewired brain be rewired again? The answer is yes. Stuart Gatehouse has repeatedly shown clear evidence of acclimatization when patients are provided with enough stimulation to induce cortical learning.

Michael Merzenich has -- says plasticity exists from cradle to grave, but practicing a new skill under the right conditions is essential to invoke millions if not billions of new neural connections within the brain.

And Kevin Monro has concluded that speech must be amplified to significantly new higher levels of audibility than previously experienced if any shot at meaningful neural reorganization is to occur.

So the auditory brain can be coaxed to change, to learn, to process once absent speech cues again over time. But this result requires two things -- meaning restoration of audibility of those speech cues as part of the patient's new listening experience and guided, attentive practice.

Through speech mapping, an objective tool -- clinical tool using probe microphone technology, a tool that is unavailable to anyone self-treating, hearing care professionals can define sound pressure at the eardrum across

critical speech frequencies. Sound that are just audible, the red line, and intolerable, the asterisks.

This defines the hearing range in the patient's ear where sounds are both audible and tolerable. In a patient with normal hearing as depicted here, the overall energy of normal conversational speech, the gray shaded area, falls comfortably in the middle of this hearing range. And since all speech sounds are appropriately audible, the associated speech intelligibility index score you see to the right is 100.

This is the hearing range of a pretty typical mild to moderate age-related hearing condition. The kind of condition the PCAST has identified as particularly suitable for self-diagnosis and treatment.

With this hearing loss a great majority of the speech sounds fall outside of this patient's listening range and the associate speech intelligibility score is very low, a 28.

Using the same probe microphone

technology audiologists can measure speech energy in the ear and adjust hearing instrument settings to achieve desirable aided goals. The aided speech result you see here in pink is ideal and yields a speech intelligibility index score of 70. A result that typically is not often achieved even when fitting software programs to a given target.

In this case a lot of speech zones are now back inside the listening range. As a result, the result would also sound very unacceptable to the patient initially. So guided adjustments over time working towards this result with coordinated listening practice can get patients comfortable with this ideal solution.

This is the definition of best practice and it should be the minimum criteria of care for anyone with any degree of communicatively confounding hearing loss. Without speech mapping subjective sound quality is the only guide.

And first-time users will use it to under correct as exemplified here with aided speech audibility barely different than unaided.

And an SIR speech intelligibility index barely different as well of 41.

This will happen regardless of the hearing device type or class that's being used. And treatment that is assumed to be effective, but actually isn't is often described as a placebo. An unaided speech intelligibility score of 28 translates into 30 percent speech understanding.

A self-treatment score of 41 translates into 52 percent speech understanding. A clinically guided score of 70 translates into 90 percent speech understanding. Thus, the guided approach offers the best opportunity to improve communication and as a result positively impact comorbidities.

My message to consumers that I am happy for the FDA to hear if your provider is not objectively verifying aided speech audibility in your ears and providing therapeutic guidance to reach goal amplification performance, find a new provider.

And the clinical guidance -- this same

clinical guidance can both direct and identify the potential and the limitations of any hearing device including PSAPs, a factor that should be critical in making consumer decisions.

As far as consumer cost is concerned consider the following: Small independent hearing care practices who serve 60-plus percent of the market pay 200 to 400 percent more for the same hearing devices purchased by the VA or Costco. The two lower cost examples used by PCAST.

This is due entirely to their purchasing volume. And this difference can be as much as $1,600 or more per patient. If small hearing care practices were encouraged to purchase together through a national group purchasing organization, they could not only be the single biggest volume buyer, they could command some of the lowest wholesale costs.

This is a significant way to lower consumer costs without bypassing important professional care by going over the counter. It is the solution overlooked by PCAST. And since

this group purchasing infrastructure already exists, I have another message for consumers that I'm happy for the FDA to hear. Demand that your providers purchase this way.

In the February issue of the Hearing Journal of this year I wrote an article called the "Counterpoint to the PCAST recommendations". It is on the FDA docket. I would encourage you to read it. Thank you.

DR. EYDELMAN: Thank you very much. Mr. Robert Artigues, please?

MR. ARTIGUES: Hello. I'm Robert Artigues, vice president of General Hearing Instruments. It's a pleasure to speak to you today.

General Hearing Instruments is a U.S. Class I/Class II medical device manufacturer producing hearing aids since 1984. Awarded 24 patents, our organization is dedicated to the hearing health sciences and tinnitus research participating in several NIH brands.

Our mission is to provide value-driven

hearing solutions without compromising in quality, acoustics, design, technology, or craftsmanship driven to produce high-quality transparent sounding hearing aids that stimulate the auditory system in efforts to retain without the need of obtrusive sound processing systems.

As we all know, the hearing loss population is underserved. 75 percent of those with a hearing loss have a mild to moderate hearing loss. Only 10 percent of the mild to moderate hearing loss population seek professional assistance.

There are a number of reasons why those with a mild to moderate loss forego hearing assistance. The biggest reason is the delivery model, the medical model, and the business model.

These models do not appeal to those with a mild to moderate loss because of complexity, cost, and financial risk. The complexity. The right hearing professional must be identified and several visits are required. Cost. Two hearing aids can cost thousands of dollars. And as a

patient stares at their smartphone recalling the cost they ask why. And financial risk. The fear that the hearing aids won't work well and a refund may be difficult to obtain.

The current model does not ask the consumer what they want and we wonder why they do not accept the model not designed for their interest.

Almost 20 years ago General Hearing Instruments recognized this problem and developed an innovative delivery model specifically those with a mild to moderate loss. This model is based on the principles of simplicity, value, and risk free.

Simplicity. The aids are available on the Internet and retail pharmacy departments. I can discuss where offline. Multiple visits to a professional are not required. Easy. These aids are easy to use with minimal controls programmed for the mild to moderate hearing loss population intend to deliver high quality sound amplification without the need of intrusive features allowing

the brain to hear again.

And value. These hearing aids are high quality digital hearing aids manufactured in the U.S. under full FDA regulations. They have basic features needed by the MML population, but not the more exotic features that provide little benefit to this population that just drive up cost. And two hearing aids can be purchased for under $1,000.

Risk free. Because our hearing aids come with a 90-day, 100 percent money back trial period and a one-year warranty. This motivates the mild to moderate loss population to purchase hearing aids privately, affordably, and easily. They discover what hearing aids can do for their quality of life risk-free, motivated to continue using hearing aids even after they outgrow basic hearing aids.

Designed to be starter hearing aids we are seeing the emergence of customers transitioning from a basic hearing aid user to custom programming consultation.

Now, GHI has been extremely successful delivering an innovative hearing aid model to the mild to moderate hearing loss population through multiple -- multiple fortune 500 companies.

Most importantly, this has been achieved while manufacturing hearing aids under full FDA Class I medical devices as the same aids will abide by the new good ID system.

In addition, these aids are sold over the counter with restrictions. Restrictions on age -- age, the review of red flags, and the processing of the medical waiver.

A restricted over-the-counter program can serve the underserved mild to moderate hearing loss population without diminishing quality systems regulation that is intended to protect the end user; not the specialist, not the manufacturer, or the supply chain.

The reduction in QSR and good manufacturing practices is a moot point due to the fact that most major electronic manufacturers abide by ISO quality systems which is a

prerequisite in obtaining a Veteran's Affair contract. Innovation is not being held back by quality systems regulations and good manufacturing practices.

The restriction release or current stance on PSAPs will dissolve the term hearing aids as we know it today. Augmented reality hearing is becoming the new hearing aid. Sound preference calibration is becoming the new hearing test.

Current restrictions to PSAPs will stimulate creative marketing to subvert all regulations through alternative labeling. By allowing PSAPs to label intent addressing a hearing loss you're potentially incentivizing medical device manufacturers to abandon FDA registration costing -- causing a loss in jurisdiction to control power output reaching a severe to profound hearing loss community that are served by the hearing health professional.

Any hearing aid manufacturer will tell you that PSAP is a hearing aid. One website the

product is called an amplifier, but on the same product -- the same product on another site is called a hearing aid.

I don't believe the Department of Defense shares our same problem and semantics. Semantics in our industry is used to subvert regulations overriding public safety.

Now, GHI supports a creative of a special category of basic hearing aids for the mild to moderate population provided there the following restrictions:

The aids must be Class I medical devices manufactured under full FDA regulations. They must have limits on gain and output to only serve the mild to moderate loss population. And that they're sold over the counter with restrictions. They must be 18 year old to purchase, must review the red flags, and process the medical waiver.

Why? General Hearing Instrument's, a medical man- -- medical device manufacturer, is already operating by these measures. It can be done. It is being done.

Now, GHI has demonstrated that it is possible to innovatively deliver quality hearing aids to those with a mild to moderate loss while operating under full FDA regulations govern -- governing the manufacturing and sale of hearing aids.

It is unnecessary to weaken or eliminate these regulations to resolve the issue of a hearing aid adoption. Doing so will only subject the individuals of a mild to moderate loss population to potential harm for no value -- no valid reason ultimately evading safety and efficacy.

If anyone has questions about this model, its consumers, or their demographics, just ask. I've been here the whole time. Thank you for your time. I look forward to our conversations.

DR. EYDELMAN: Thank you very much. Mr. Thomas -- Earl Johnson?

MR. JOHNSON: My name is Earl Johnson and I'm here today on authorized travel from my employer, U.S. Department of Veteran's Affairs. I

also work as an associate professor at a local university and practice audiology on my own.

One thing I'd like for you to take away from my presentation is that the quality of the manufactured product is not all that the wearer should receive.

Now, the primary purpose of providing better hearing is to improve quality of life, but its provision is encased in a multitude of forms. I'd like to take a minute to talk to you about those forms.

Form one we know is for the non-hearing impaired consumer is the PSAP. The remaining forms are the case history hearing evaluation waiver or clearance.

Within form two, the person has hearing loss, but it can be a self-fitting software first hearing aid delivered over the counter or by mail with almost no service.

Form three is form a person with hearing loss, but would require face-to-face delivery with hearing aids and a verified prescription along

with personal adjustment counseling as well as some follow up and fine tuning visits to help that person adjust to their hearing aid and make forward progress.

Form four would include the individual person no matter what their hearing loss. Not just treat the hearing loss, but look at the whole person. Included would be those things in form three, but also thoroughly addressing these personal listening goals and one's communication needs which are sometimes very different than just having hearing loss. It can also include immersive participate in rehabilitation programs.

It almost seems like forms two, three, and four, they're operating in the free market with equivalency in some perceptions and practices. But I'd like for us to consider whether these forms are indeed equal in terms of the level of care that providers are capable of delivering and, two, the outcomes of real patients with hearing loss.

It can be for infants as young as this

receiving a hearing aid for the first time or for the elderly wanting to main- -- be socially active, maintain their communication with other people around them not sure how to proceed with a hearing aid.

Let's change gears a little bit and talk about hearing amplification in society and I'll share with you a failure to uptake. You might recognize this lady. She advertised this product with "I've fallen and I can't get up."

But even though it's over the counter and has some reimbursement only 5 to 10 percent of the 7 million or so individuals who could benefit from one actually have one.

By comparison, then, hearing aids with much higher adoption rates could arguably be a real success. But that hasn't stymied the rise of gerontechnology. There's been many advances since her day. We have smart pillboxes. We have all kinds of wearable technologies.

But there's a strange incongruity that exists between what science makes available and

what society will make use of. Let's call it the Edith or the Ed paradox.

Here you see a younger Ed versus an older Ed. One thinks the solution is technology and things that are more immediate. He may not have any health concerns whereas this may have -- this person may have many competing concerns. Hearing loss may be at the back of their mind whereas hearing aids are at the front of their mind asking why are there not coverage for things like my medicines and eyeglasses.

So rather than just a technology solution, consider that there's about 35 million people that have enough hearing loss to actually need help in this country. But with hearing aids only needing to be replaced about every five years, the adoption rate's only 2 million people actually seek hearing aids each year. This is not consumer electronic device volume and the demographics of the people are entirely different.

Real growth depends on a patient/provider relationship to lessen emotional

barriers and to provide standardized care. Consider that the marketplace has been shown to be inelastic. Lower prices will not increase that demand.

In other countries with deregulation adoption rates are lower than they are here. And a large evidence base already supports quality delivery to encourage uptake and outcomes.

So when formulating an effective, safe, and sustainable solution consider that usually form follows function. What function is trying to be accomplished?

Putting a product in the ears of every person wanting to hear better or ensuring successful uptake and positive outcomes for persons with hearing loss.

When you consider that second function you see the importance of form three and form four. It is true that form three and form four require more effort to deliver them, but it's also true that there's greater return on that effort. I defer to this document for other countries that

have considered these forms of delivery.

And lastly, that better forms of delivery are already affordable. Using a quality adjusted life year as a measure of quality and quantity of life lived, a cost utility analysis revealed that the cost to better forms is only about $1,100 per person.

Hearing aid treatment per QALY was only $60. And when you add rehabilitation to that, for example, in a government supported program like Department of Veteran's Affairs that QALY drops to $32 each.

In comparisons, Evans et al listed these common medical procedures that are readily available to people who need them. The QALY cost is this per QALY compared to $32. If necessary, contemplate the cost to subsidize better forms, if necessary.

Current national demand is about 3.3 million units. This was four time Department of Veteran's Affairs dispensing at 825,000 units and national cost then would be about 2 bil- -- $2.2

billion for product and better delivery. Without a present coverage to hearing aids the national Medicare budget is 600 billion. This would represent only a small increase in expenditures.

If adoption rates did all of a sudden increase to 40 percent like it does in other countries with some subsidized healthcare, demand increases to about 5.4 million units and that's still less than 1 percent of current Medicare spending.

I leave you with this quote: "That in the presence of demand for access and better hearing possibly allowance for many forms, continue to place forms -- place value on forms three and four." Thank you.

DR. EYDELMAN: Thank you. Mr. Thomas Tedeschi?

DR. TEDESCHI: Hello. And thank you for the opportunity to comment today. My name is Dr. Thomas Tedeschi. I am the vice president of training and development for Amplifon Americas and hold a doctoral degree in audiology from Central

Michigan University and a master's degree in audiology from Brigham Young University.

I've been an audiologist for 40 years and have worked in hospital settings, private practices, manufacturing and distribution both domestically and internationally. I'm a member of the American Academy of Audiology and the Academy of Doctors of Audiology.

We have concerns that acceptance and utilization of PSAPs beyond their intended use is a step back in time. More akin to hearing aids of the 1960s and vastly superior devices in the hearing industry today exist.

There have only been a few studies which compared premium PSAPs to hearing aids in various noise conditions. These studies utilized hearing healthcare professionals in the examination, testing, and adjusting of PSAPs and hearing aids.

To our knowledge there have been no studies conducted that did not involve hearing healthcare professionals. This is contrary to the proposed regulatory changes allowing the consumer

to self-diagnose, self-select hearing solutions, and self-treat their perceived hearing loss.

The primary concern of a person with a mild to moderate hearing loss is to improve speech understanding in noise. The results of these studies found that PSAPs did not achieve the desired results and all subjects preferred basic hearing aids to premium PSAPs.

MarkeTrak is the only study revealing data about decision and purchase patterns of PSAPs. MarkeTrak showed three key points concerning outcomes.

Point number one, most PSAP users paid less than $50 for their device. We examined numerous PSAPs in the price range under $100. In addition to producing harmful maximum outputs greater than 120 dB, there is no consistency whatsoever with regard to frequency response and volume gain. There is also a lack of features necessary to improve speech understanding in noise.

Point two, 41 percent of PSAPs users

purchased binaural devices as compared to 80 percent for hearing aid users. Age-related presbycusis consists predominantly of bilateral symmetrical hearing loss. The standard of care is to fit two hearing aids in order to provide improved speech understanding in noise. By fitting only one device the benefits of the hearing aid are reduced and they are marginal at best with a PSAP.

Point three, the median usage of hearing aids is ten hours per day producing customer satisfaction of 85 percent. The hours of usage are a clear indicator of customer satisfaction. Direct mail consumers wear their devices only three hours a day which we believe is the best indication for PSAP usage. Dissatisfied patients will likely delay proper care, run the risk of increasing the stigma related to hearing loss as well as increasing the risk of additional medical issues.

Untreated hearing loss may grow worse over time as the brain becomes less effective in

its ability to process sound. It is likely to lead to depression and other comorbidities related to the cognitive decline resulting in increased healthcare costs.

In support of this a 25-year French study found no difference in the rate of cognitive decline between people with no reported hearing loss and people with hearing loss who used hearing aids.

By contrast, untreated hearing loss was significantly associated with a decline in cognitive function. Also a recent study published in the Journal of the American Medical Association found that individuals age 55 to 64 with diagnosed and untreated hearing loss had 33 percent higher healthcare costs when compared to patients without hearing loss.

Based on all these arguments we believe that the creation of an over-the-counter category for hearing aids will be a huge step back in technology sophistication and will lead to less customer satisfaction, lower adoption, and

healthcare -- and higher healthcare costs.

This is supported by the significantly lower customer satisfaction and adoption rates in Japan where regulatory framework is in line with the suggestions made by PCAST.

In conclusion, the lay person is unable to reliably self-diagnose, self-treat, and evaluate their hearing loss; two, PSAPs are potentially dangerous to the hearing health of consumers due to high maximum output; and three, PSAPs lack the features to produce any benefit for the number one reason people seek assistance -- speech, understanding, in noise.

Accordingly, we urge the FDA to continue its current regulations regarding the safety and efficacy of hearing aids and to continue its encouragement of strong state licensing requirements for dispensing professionals to fully satisfy and protect consumers' hearing healthcare needs. Thank you.

DR. EYDELMAN: Thank you very much. Ms. Noreen Gibbens, please?

DR. GIBBENS: Good morning. I'm feeling a little lonely up here. Thank you for taking time and staying and waiting for me this morning. I want to talk about my experiences as a hearing healthcare provider. I'm Dr. Noreen Gibbens. I'm a clinical audiologist. I've been in hearing healthcare for over 30 years.

I want to talk about my experiences based on my employment in large dispensing programs such as Henry Ford Health System, Vanderbilt University, and then more recently I was the lead audiologist for High Health Innovations which is the United Healthcare hearing aid program for the Medicare Advantage members.

I'm assuming everyone in this meeting knows that if we change labeling and regulations we change access to hearing aids potentially creating a much larger direct-to-consumer approach. While that might seem like a real win for consumers, I'm afraid that we are taking some information and making some very flawed assumptions about that.

I'd like to talk about three subjects today. One you've heard a little bit -- well, you've heard a lot about, the ability for consumers to self-diagnose and know when to refer themselves to a professional.

The other is the misguided use of using vision and vision care as an equivalent to hearing and hearing care. I'm not sure just because they're both senses how we got to the point where we're comparing them so often, but they are not the same.

And I also want to talk about the importance of appropriate testing and the need to assess the many non-traditional hearing tests that are flooding the market.

My first concern again is self-referral. Describing one's hearing ability is a real challenge when hearing loss is present. And most often the description is not consistent with the test results that we obtain.

I tell you that after testing thousands of people and taking case histories on thousands

of people. Sometimes the results are predictable. Sometimes what that patient has told me is completely different than what I wind up finding in their testing.

I also want to talk about the idea that over 90 percent of hearing loss is not treatable through medicine or surgery. That does not make that consultation unnecessary. We who work in the clinics know that on a given day in a hearing healthcare retail or medical setting you can have anywhere from 10 to 50 percent of those new patients coming in that wind up needed a referral.

We often use the statistics and the average hearing loss numbers and all of these different surveys and that sort of thing to guide decisions, but I will tell you having worked in clinics I know the picture is very different. The people showing up have very complex problems no matter where one is employed.

Hearing loss is also not comparable to vision for a few reasons. Age-related vision problems lead mostly to an inability to see print

-- and I'm going to put these on -- which is fairly obvious to an individual. I can read a whole lot better right now.

I say that jokingly, but I also say it seriously. Seeing or reading is something we can usually tell we're having a problem with and using some sort of magnification leads to a resolution of the problem.

Persons with hearing loss cannot often tell they're having that same difficulty. Family and friends may be bringing it up to them. Some in my profession might call that denial, other family members might call it selective hearing. But a person with hearing loss, especially a high-frequency loss, is often unaware of the problem.

When there's low and mid-frequency hearing problems, it's more obvious to them. Turning up the volume does make it easier under headphones in certain conditions and that sort of thing. But other than that they don't really have a good idea of what their hearing loss is.

We fill in a lot of gaps when we don't

hear things, and sometimes we're correct and sometimes we're not. But we can -- we can function with hearing loss more often. I know that a few people in this room will argue with me on that one, but we can function more easily and independently with hearing loss. With vision loss it's very different. If you can't see to drive, if you can't see well enough to read, you're very well aware of that.

My third concern as I mentioned is the non-traditional testing that is available. We're focusing a lot on hearing aids today, but we're not focusing on those devices, those audiometers and different devices that have been used to assess the hearing levels.

I'm not impressed with the ones I'm most comfortable with. I will tell you that right now. They can lead to completely inappropriate recommendations and outcomes.

Small differences in the decibel scale are actually very large differences in sound pressure level. And I want to especially point

this out to people in the room who might not be familiar with the decibel level. It's a logarithmic scale. Small differences mean very large differences in sound pressure level.

Probably the best example is the OSHA requirements. OSHA says that a worker can be exposed to 85 dB of noise for eight hours. If the sound level around them is 88 decibels, the time is cut to four hours. And if it's 91 decibels, the time is cut to two hours. That's a 6 decibel difference. These are not pennies. These are big amounts of change.

A logarithmic scale we can get into that later on and you might hear some more about that this afternoon. But I do want to point out these things matter and we're kind of trivializing the hearing testing and the diagnostic care that needs to take place.

I want to also point out that there's been a great deal of emphasis on the hearing loss in the baby boomers, the 60 -- 50, 60, 70 year olds and targeting the market that would buy these

devices for mild to moderate hearing loss.

Anybody in the room know what the largest segment of the U.S. population -- the largest growth age group is? Right now it's 85 and older. That is the largest growing segment of the population. This is a group that is very susceptible to fraud and needs much more assistance than what we're currently recognizing.

We need to take hearing loss seriously as a country. I can tell you individual examples. I can tell you wide-scale examples of why I feel that way. I believe that it's very important to start pursuing some changes, looking at our delivery system.

We don't have a product problem. In fact, we have some great products out there. It's the delivery system, the maintenance, the care, the follow up that needs to take place.

And for anyone who's new to dispensing or distributing, selling hearing aids whether it be individual sales or large groups, you're going to be a little surprised at how much work it

actually takes. You need well-qualified educated people back in your manufacturing facilities to provide the appropriate service that I expect as an audiologist and I expect for my patients. I shouldn't have to intervene and argue with you about whether a hearing aid is covered under warranty. And I got pretty used to that over the years.

Again, we have some really good products out there. Those hearing aids should last three to five years. They should not need replacing every year. So we need to focus on those products, but also the better solutions of getting access for our consumers. Thank you for your time.

DR. EYDELMAN: Thank you very much. We will now ask the next 12 public speakers whose names are currently displayed on the screen to make their way up to the front table.

When your name is called please step up to the podium, state your name and any organization you're representing for the record.

After you have finished presenting please return to your original seat in the audience.

Mr. Laureyns, please step up to the podium.

MR. LAUREYNS: Thank you very much for the invitation and the possibility to give a talk here. My name is Mark Laureyns. I'm President of the European Association of Hearing Aid and Hearing Care Professionals. This presentation is a joint presentation. Also in name of EFHOH, which is the European Federation of Hard of Hearing People.

We are, of course, European. That's what I stated. Interesting enough, EFHOH is very active in the north and middle of Europe and II's very active and present in the middle and the south of Europe. So together joining forces we cover nearly all of Europe. That's good.

And we see you have positive things about association and we do cooperative quite actively. If you don't listen to the customer and the client, you're making a mistake. I think it's

very important that hearing care is in line and very close to what the end user is expecting.

We also made a joint statement on the safety issues we see with PSAPs on European market and you will see that we are looking into joining forces with multiple other associations like the World Health Organization and the European Commission on this account.

What are PSAPs? I took the FDA proposal. So PSAPS are intended for non-hearing impaired customers, consumers to amplify sounds in the environment for a number of reasons such as for recreational activities.

In fact, PSAPs are intended to amplify for people with no hearing impairment. That's important because it's people that typically should have quite normal hearing.

What kind of PSAPs did we see? I think it was, in fact, European Federation of Hard of Hearing People that asked us to look into this because they were concerned. They had seen some dangerous PSAPs being sold in middle and north of

Europe and they wanted to look into this.

And also their members were quite confused because a lot of them just looked like hearing aids. And sometimes were blurred in communication.

So the first you see is devices that look like BTE hearing aids. We had 17 products like this. Then you've had 6 products that look like an IDE -- ITE in the ear hearing aid. And then we have an interesting category and it's coming up. They look like Bluetooth headsets, Bluetooth receivers. The only thing which is blue is a light because there's no wireless communication at all, but they operate like an amplifier. So they do the same.

And then we found to our big surprise because we started analyzing one after the other and then we saw 120 dB SPL, 127, one was even 130. Honestly we were shocked. We expected to see a little higher output levels, but these were crazy.

Now, just to read what these levels mean, if you have an output level of 130 dB it

means pain threshold has exceeded 120 ambulance siren, pneumatic drill, and rock concert levels. That's what we are talking. And 140 is a jet plane taking off next to your ear just to have a reference of what we're talking about.

The risk effect is sudden damage of hearing. That's acknowledged. I think that it's a document from the European Commission. Even 85 dB can already start leading to hearing loss and tinnitus so you need to be careful with those levels.

Here's the analysis where we used, of course, reference equipment and all university settings where this was tested. You see a very typical design I think you see here. If you look at that device they have a peak response, a lot of low frequency, mid-frequency gain.

Now most of the people that need better understanding, need more high frequencies to understand better. But if you have a device like this you won't understand that well because you have too much mid/low-frequency gain. So what do

you do? You increase the gain which means even more risky. You get very high output levels.

So here are the norms we have tested. And here are all the devices on the list. You'll see all of them one to the other and you see all these devices, each and every one of them, had an output level that was higher than 120 and they went to 135 dB SPL. Shocking.

So and is this unsafe? I heard today some people comparing PSAPs to these reading loops or reading glasses you can buy. I think this is quite something else. Putting a loop in which is not fitting right you may see a little blurred. If you put a device in your ear with an output close to a jet plane taking off, this can create sudden hearing loss. So we are talking about two very different things here and we want to be safe.

I think also the World Health Organization has an action called "Make Listening Safe." It started last year. There's a lot of stakeholders involved. And here again you see that these PSAPs are much louder than permissible than

those that you should get; this is quite dangerous.

Where are we in Europe? In Europe the European Commission has a directive that has been specifically developed for personal music players. And I think that this directive is saying that personal music players shall be designed and manufactured in a manner that ensures that under reasonable, foreseeable conditions of use they are inherently safe and do not cause hearing damage. I think the same should apply to PSAPs.

And here are some limitations they suggest. They say that exposure sound levels should be limited also over time because it's not about the peak, it's also the time you use it and you wear it. So if you have devices with 80 dB A output, you should limit the use to 40 hours per week. If they have 89 dB A you should limit the use to 5 hours per week. They don't talk about devices having 130 dB SPL because we all know this is crazy. Also they need warning signs.

Are all PSAPs and all personal music players bad? Not really. There are some safe

devices out there. We have one we've analyzed recently and it is clearly mentioning that they respect the European guidelines. The maximum volume level in which this device can be used is currently at 85 dB according to the European regulations. So it's possible.

Sometimes we get a reaction that these players need to be louder to give good sound quality and to give good music quality. I have a set in my pocket here. Honestly the music sounds great even at reasonable levels which are not unsafe so I wouldn't take that too serious. The sound quality can be good if things are safe.

Here's the joint activity of the World Health Organization so they have a joint stakeholder consultation on the 1st of October 2000- -- October 2015. And, in fact, here you'll see the conclusion of the report.

On the meeting report they state that personal sound amplifiers, devices used to facilitate listening for people with normal hearing, were also noted as an important device

which could be considered for inclusion in this initiative.

Here again, support for doing something about it. And that's also what we are taking forward now in discussions with the European Commission because this guideline on personal music players has to be modernized.

Today it's not just a simple MP3 player anymore. We have hearables, we have devices you connect to your smart devices which is good. We're not in disfavor of all of this. It's a normal evolution. Clearly we have to be very sure that things stay safe.

So to conclude, we did analyze 27 cheap PSAPs on the European market and they all had output levels higher than 120, one even reaching 135 dB SPL. PSAPs should and shall be designed and manufactured in a manner that ensures that under reasonable, foreseeable conditions of use they are inherently safe and do not cause hearing damage.

And that's our main message. Make them safe. Make sure that people that have normal

hearing or maybe a mild problem don't become hearing impaired because of the use of devices which are unsafe today. That's what worried us about the PCAST report at some point that, in fact, safety issues would be disregarded. So please make them safe. Suggestion could be limit them to 85 dB A. That's a good point. Thank you for your attention.

DR. EYDELMAN: Thank you. Ms. Cindy Beyer?

DR. BEYER: Hello. My name is Dr. Cindy Beyer and I'm the vice president of Professional Services at Hear USA, a nationally accredited hearing care organization.

Hear USA owns and operates over 200 hearing aid dispensaries and a network of over 4,000 licensed hearing providers. Hear USA was founded in 1987 by a physician who sought to raise the clinical standards of hear- -- of retail hearing aid companies and to secure third-party coverage for medically necessary hearing services.

Hear USA has worked to bring

accountability, affordability, and accessibility to millions of lives through a managed hearing healthcare system. Oops. Yeah.

Over the past 30 years Hear USA has become an innovative leader in managed hearing care. Today over 75 percent of our patients are directed from health plans, employer groups, and other benefit sponsors who embrace the role that an accredited health network brings in providing quality hearing care products and services.

These plans provide coverage not just for the FDA regulated hearing aids, but for the ongoing professional services that are required to achieve positive patient outcomes.

These services include patient medical history, the examination of the ear, the evaluation of the auditory system, an assessment of visual, cognitive, and dexterity function, hearing aid programming, conformity, and ongoing RO rehabilitation services.

These best practices form the cornerstone of Hear USA operations and are at the

very heart of our third-party payer relationships. Best practices have been positively correlated with increased patient satisfaction.

In 2014, MarkeTrak reported that consumers are significantly more satisfied if all best practices are employed by the hearing professional. In fact, overall consumer satisfaction with the current hearing aid dispensing model in the United States is over 80 percent. This is in stark comparison to countries where hearing aids are not regulated and the satisfaction rates fall below 40 percent. Likewise, hearing aid owners report very high satisfaction with their providers, over 93 percent.

The value of the professional service component in the hearing aid fitting cannot be overstated. The VA, the single largest provider of hearing aids in the country, recognizes the critical role the audiologist plays in the provision of hearing care.

Hearing loss is not a benign condition.

The FDA has long recognized that the hearing health interest of the consumer are best served as a part of a medical model of care.

In 2008, the National Council on Aging reporting that hearing loss is associated with physical, emotional, mental, and social well-being. For many people uncorrected hearing loss is a serious health issue if not a life or death issue.

Further, the Archives of Internal Medicine reported that hearing loss can be a disabling condition and that these disabilities impede healthcare access and use with possible adverse consequences to health and survival.

Millions of Americans have access to hearing aids at reduced, out-of-pocket cost thanks to full or partial insurance coverage. Actions taken at the federal level to minimize the importance of medical devices in the treatment of hearing loss could very well result in decreased insurance coverage and also have an adverse effect on access and affordability.

An estimated 30 percent of Americans have some type of coverage for hearing aids. This includes 40 percent of the 17 million that are enrolled in Medicare Advantage plans.

There are 70 million lives in Medicare and CHIP programs, the majority of which also cover hearing aids and related services. Millions more have hearing aid coverage through self-funded commercial and other types of hearing -- of health insurance.

In 2012, MarkeTrak reported that insurance coverage is the single most important factor in the decision to use hearing aids. 67 percent reported insurance coverage to be the primary influencing factor.

The deregulation of hearing aids may put millions of Americans at risk for losing hearing aid coverage thus impeding access to medically necessary assistance. We should not lose sight of innovation that has brought us third-party reimbursement, best practices in telehealth audiology, as well as wireless, Bluetooth, and

smartphone compatible hearing aids.

Thanks for FDA regulation, major investments in R and D among the manufacturers, and the adoption of best practices in the professional community hearing aids today are smaller, smarter, more comfortable, and more effective than ever.

Even with these advancements the average price of hearing aids has dropped by several hundred dollars in the past few years. This is evidence of competition and market forces at work.

In addition to reduced out-of-pocket costs, Americans have access to licensed hearing care providers who are accountable under state licensure boards to deliver safe, ethical, and effective care.

Removing the professional component of the hearing aid fitting may take us back to those dark days when dissatisfaction, disappointment, and disdain were general perceptions.

The Hear USA story is characterized by continuous improvements and access to services and

affordability of products. The task at hand is to continue our forward progress to a higher standard of medically-based care rather than to retreat to a flawed system that will inevitably result in poor outcomes, increased patient risk, and reduced access to quality hearing healthcare. Thank you.

DR. EYDELMAN: Thank you very much. Mr. Pavlovic?

DR. PAVLOVIC: Good morning. I'm Chas Pavlovic. I'm presenting this as a private individual from Palo Alto, California, who has been involved for 35 years in all aspects of hearing health delivery.

First I was an audiologist for 15 years, professor of audiology at University of Iowa, University of Mississippi and University of Provence in France. I was R and D leader for major hearing aid manufacturer ReSound for ten years and then GN Sound.

And I was al- -- I am now and was before R and D leader of Hearable Companies. I purpose don't say PSAP because I think hearables are much

more portant (sic) devices. And as executive VP at Sound ID and then as a COO and owner of BatAndCat Corporation.

First as a hearing aid -- former hearing aid manufacturer a couple of comments. In the 20 years, from 1980 to 2000, we saw a tremendous growth of hearing aid technology. Just to remind you, we saw direction of microphones, miniature ITs and ITCs, we saw first programmable devices at ReSound, we saw compression, we saw feedback insulators -- insulation, digital hearing aids, and open platforms that were actually as portant as computers at that time, which unfortunately is far from the truth nowadays.

We have open platform DSP ReSound Air, open devices, and finally the environment recognition algorithms all before 2000.

Since then the rapid innovation has virtually stopped. The product is essentially the same across the big six manufacturers. The industry has failed and failed miserably to capitalize on the amazing capabilities of modern

technology such as computing power of smartphones to both process sound and provide intelligent fit to the environment, which, by the way, can surpass any fitting based on prop 2 measurements because these people don't have the -- the adaptation issue and can adjust to their preference at any time, at any moment.

Computing and storage power of Cloud to support, you know, algorithms has not been utilized. Sophisticated telephone networks that transmit information and connect patients and audiologists has not been utilized either.

We have an extraordinary product cost. Not com- -- not uncommonly 50 times BOM, bill of material, as opposed to 2 to 3 times BOM seen in the consumer market.

As a bottom line, we also have an industry -- this is not on the slide -- that has failed 75 percent of its customers. Industry that's failed 75 percent of people. Keep that in mind.

From the audio- -- now from to the

audiologist point. I have the highest possible respect and regard for this professional which fully makes the Au.D. title that I, among others, worked hard for.

Unfortunately due to a uniformity in current hearing aid offerings our profession is now in a potential conflict of interest situation by acting as a dealer for only few select manufacturers. And more and more frequently accepting to work for the chains directly owned by a single manufacturer.

Now Hear About Design viewpoint my newest profession this is a young and nimble industry capable of incorporating modern and powerful consumer technologies. As a direct consumer industry it can provide for low product cost, 2 to 3 times BOM as I mentioned. And already a number of promising developments exist both as devices as -- and as fitting methodology.

There's quite some research -- we heard about this this morning that this is not correct. But there's quite some research proving decisively

that people can adjust and adjust even better than the prop 2 measurements.

Also as an SAII inventor and the (indiscernible) standard I can tell you that SAII based on the threshold done for the instrument is more precise than prop 2 measurements.

With respect to PCAST recommendation I fully support all PCAST recommendations. If adopted these will provide solution for 30 million Americans who do not have hearing aids due to the extraordinary cost. And also, which is not in the report, to poor performance noise and the vibration. Exactly where people with mild to moderate hearing loss need help. So the only condition people need hearing aids they fail. Something which is easily correctible by a number of medical devices that we can design.

Also I would like to add couple of things that should be added to the PCAST recommendations that actually heard that this morning. Provisions need to be developed to ensure the maximum sound output and gain are

consistent with mild to moderate hearing loss requirements so shall also be safe. And that's easily done, very easily done.

And then for devices respecting USR regulations consumer manufacturers may provide means if they want to for the audiologist to override gain and power limits to fit severe and profound hearing loss. That way an audiologist can turn at will and adjust such a PSAP into a powerful hearing aid.

Chance the audiologist will have access to an even greater number of highly competitive devices which will drive innovation in the professional market, as well.

One comment on the Class II devices. That you should not forget them from the PCAST recommendation. I'm not sure they did, but it's not quite clear.

These devices actually provide better signal-to-noise ratio than Class I devices. And I can mention lapel microphones here. They provide 16 dB signal-to-noise ratio improvement which is

far better than any directional microphones. That way they also report a less sound output. So actually you have safer devices, by far safer than hearing aids.

We also heard the radiation is an issue. It is not. Consumer electronics is well regulated, group two devices are well regulated, FTC takes good care of that. Devices are thousands times or more safer than phones and are not looking at any additional exposure there.

So in conclusion as a hearing aid manufacturer I'll be happy that I took and participate in direct consumer sales and access four times more people than before. So I have increased market as a consumer manufacturer, as a manufacturer. As an audiologist I will be happy that I can have solutions for 75 percent of people. I will also be happy to have many new and innovative ultimate new solutions and not be tied to only a handful of expensive products. And I will fully enjoy that I can fully exercise my profession to offer best solutions to the patient

within any -- for the patient.

DR. EYDELMAN: Thank you.

DR. PAVLOVIC: And finally as a PSA manufacturer I will now be able to deploy all my resources to harness the relevant consumer technologies and help people to hear better noise if somebody has a hearing loss. Thank you.

DR. EYDELMAN: Thank you very much. Mr. Brent Edwards, please?

MR. EDWARDS: Okay. To start I'd like to thank the FDA for the opportunity to speak today. And I'll let you know that my comments today are my own and I do not represent any company or association here as will become apparent.

My name is Brent Edwards. I'm the CTO of Ear Lens and I've spent the last 21 years developing new technology for the hearing aid industry working at both large hearing aid manufacturers and small hearing aid startups over my career.

And I would like to address three

premises that were proposed by the PCAST report that I believe are largely responsible for our discussion today.

The first is that FDA regulations have impeded innovation in the hearing aid industry. So most people know that innovation -- what innovation is, but they may not know that innovation is often motivated by the unmet needs of a specific population.

So what are the unmet needs of people with hearing loss? Well, what is shown here is a partial list of the needs of people with hearing loss. And what becomes apparent immediately is that their needs are many and they're complex.

What's immediately obvious from this list is the difference between someone who needs a hearing aid and someone who needs reading glasses. Someone who needs reading glasses has one single need and it's perfectly accounted for by the provision of hearing aids.

The needs of people who have hearing loss are far more complicated. The hearing aid

industry and the research community have spent a lot of time and great effort to try to understand the needs of people with hearing loss so that they can develop technology that addresses these needs. These are some of the innovations that have been developed by the hearing aid industry to address the needs of people with hearing loss.

Now over the 21 years of my time in this career I've brought many of these technologies to market. And I can tell you from my experience of 21 years of developing these technologies that not once have I ever thought that FDA QSRs has in any way impeded our ability to develop these innovations nor have QSRs ever prevented these innovations from benefiting people with hearing loss.

I can also say that the hearing aid startup community where I work is quite healthy. And I take this as a suggestion that hearing aid innovation is healthy and not being impeded by QSR today.

Also recently it was announced that a

major hearing aid company is in a partnership with probably the hottest hearing aid hearable technology in the world which I also take as an indication that innovation is strong and healthy.

So my conclusion for this part is that based on 21 years of working this industry is that innovation in the hearing aid industry is not being impeded by QSRs in any way.

So next I'd like to address the comment that there are 27 million people in the U.S. who need hearing aids but do not have them suggesting a crisis in accessibility and affordability.

The statement is derived from estimates of the total number of people in the U.S. with hearing loss and the assumption that every single person who has hearing loss needs a hearing aid, which I believe is a false assumption.

The total population of those with hearing loss has typically been estimated in one of two ways. One way is using surveys which have been used to ask people if they have a hearing loss or if they have hearing difficulty.

Unfortunately such self- assessment methodology is untrustworthy.

Research suggests that between 38 to 61 percent of those who answer that they have hearing difficulty actually have normal hearing as measured by an audiogram and they would not benefit from amplification.

So what about using the audiogram as the gold standard for determining the population of people who need a hearing aid?

Well, unfortunately again decades of research has showed us that the audiogram is poorly correlated with the benefit or the need of hearing aids. Meaning that just because someone has a pure tone -- a PTA of greater than 25 dB HL does not mean that they need a hearing aid.

In other words, the audiogram measure is necessary, but not sufficient condition for needing or wanting a hearing aid. As an analogy, there are millions of people in Manhattan who have driver's license which is a necessary condition for owning a car, but most people in Manhattan

don't want to own a car. They don't need it. So it's the same thing here. So candidacy does not equal the need. Not everyone with a hearing loss wants a hearing aid.

So both self-assessment and audiograms overestimate the number of people who want and need hearing aids. To be sure, there are many people who do need a hearing and don't have them, but that number is far lower than the 27 million that is commonly suggested and we need to reassess what this number is.

Finally, I'd like to address the statement that entry level devices should be deregulated. There's some credible innovation in the hearable space today and that's going to continue. These are clearly meeting unmet needs of people with normal hearing.

Now if we consider the spectrum of hearing and the different populations of these needs I see three classifications and three different products and three different regulatory needs -- normal hearing, people with hearing

impairment who want hearing aids, and then this middle group who have a mild amount of hearing loss but for whatever reason are rejecting hearing aids.

Now the needs of normal hearing people are currently being addressed by hearables in a very successful way. Those with hearing loss who accept hearing aids are also being addressed by hearing aids very successfully.

Now this third group is the tricky one because they reject hearing aids. So trends are showing that this group might be able to be reached in the future if you adapt hearables in some way to provide some amount of amplification to provide need for this group.

So now each of these groups have different regulatory requirements. And I would say that for the normal hearing group they have difficulty understanding speech in noisy environments as do I so PSAPs need to be defined to be able to help people with normal hearing, understanding speech and noise without being

classified as medical devices.

To not allow them to do so will impede innovation in this area and impede the ability to address the unmet needs of people with normal hearing.

People who want hearing aids continue to need the current FDA quality regulations to ensure that hearing aids are safe and effective in a treatment of their health problem.

The challenge to the FDA is to develop reasonable regulations that allow this third group of people with mild hearing loss who reject traditional hearing aids to have access to a consumer-like experience while also getting benefit from a mild to moderate amplification. This is a difficult challenge and I don't know what the answer is.

So to summarize, QSR does not impede innovation, there isn't the underserved population of people who need a hearing aid but don't have one is smaller than as reported, and unregulated PSAPs need to be able to improve speech

understanding for noise for normal hearing people, and finally there should be reasonable regulations that should be developed to protect those with hearing loss who also allow for the needs to be met of mildly impaired who reject hearing aids and want help from a consumer-like product. Thank you.

DR. EYDELMAN: Thank you very much. Ms. Christine Gerhardt-Jewell, please? Ms. Christine Gerhardt-Jewell?

MS. GERHARDT-JEWELL: Hi. My name is Christine Gerhardt-Jewell. I'm an audiologist. I am here with the International Hearing Society. And I'll -- I've been an audiologist for 37 years and have loved every aspect of it.

This part is probably the part that I'm not the happiest with, but it's okay. I graduated from the University of Colorado in 1979 with my Master's and I've been a practicing clinician in the trenches ever since.

I'm a member of both state and national societies and I'm here in full support of the IHS

opposition to the PCAST proposal.

I'm here -- I'm concerned about the PCAST proposal because it essentially deregulates an entire class of hearing aids and it eliminates the role of the provider.

The proposal is -- makes a concerning and unstable environment and I know because I come from Colorado and we lived through a failed Colorado deregulation experience.

From 1975 to 1985 Colorado had a hearing aid dealers licensing board which regulated hearing aid dispensers and audiologists. Between 1980 and 1985 there were an average of 14 complaints per year.

In 1985 the Colorado legislature determined that the board hadn't revoked any licenses or disciplined anybody so it wasn't protecting consumers. The board was sunset and the Consumer Protection Act was strengthened in its place.

For ten years we had no regulation of hearing aid sales in Colorado. The number of

complaints rose steadily from 16 in 1986 to 100 in 1990. That's a six-fold increase.

There were a number of dispensers who came in who had lost their licenses in other states, there were people who never could get their licenses and it became a lucrative place to sell hearing aids.

There were a couple of examples. One person came every two weeks. He set up shop in a hotel room. He sold hearing aids. He would fit the hearing aids and return in four weeks for a recheck. At that visit he would declare that the hearing aid wasn't working well, he would return it for -- he would send it back to the manufacturer for repair. He did return it to the manufacturer for credit. He got his money back and the consumer was left with no dispenser, no hearing aid, and no money to actually solve the problem.

Another dispenser closed business overnight. He was just gone. People had paid for hearing aids, they didn't get them.

A third one visited nursing homes in rural areas. He opened is car trunk, we went room to room, he sold hearing aids and he was never seen again. There was no follow up on any of this.

According to the 1995 legislative records two-thirds of the documented complaints cited actual harm to the consumer. Not financial harm, actual harm. Misdiagnosis, inappropriate fittings, faulty testing, lack of physician referral, untrained providers. In other words, easy access to hearing aids at whatever cost did not solve the hearing problem.

We reinstated in Colorado hearing aid sales in 1995 and now we have the following protections: Enforcement of a 30-day return period, requiring business and professional insurance, requiring proof of provider's training and competency in the field, and prohibiting bait and switch tactics, misleading advertising, charging for services that were advertised as free, refusal to honor a buyer's request for a

refund, and importantly sales to a child under 18 without documentation of a hearing test.

Colorado isn't unique. All states afford consumers those protections for -- and they would be lost for over-the-counter hearing aids. The FDA specifically authorized the states to establish licensure and for good reason. Because before FDA rule and state licensing laws there was abuse and fraud.

When I pay my state dues I'm not paying for me, I'm paying for the consumer to protect them against harm and fraud in this area. When the regulations are enacted for consumer protections they end up missing if we go over the counter if hearing aids are sold as a commodity and bypass hearing health providers.

We are not helping the consumers at all if we don't provide information and services that area really necessary for the use of hearing aids, for the good use of hearings, or any amplification.

The target population of the PCAST

recommendation is persons with mild to moderate age- related hearing loss. Many of them are first-time users. They don't use technology in the same way that a PCAST member would envision.

They need people to help them operate devices around them. They require and they will continue to require assistance with hearing aids. They have hearing and communication problems, they have vision problems, dexterity problems, and memory problems. They are not in a position to self- diagnose their hearing loss nor is the clerk at the local retailer.

The aging population has often been uncomfortable, unwilling, embarrassed, or ashamed to complain when they feel they have been wronged even when the fault lies with the seller.

If there are problems, the PCAST proposal would require consumers to navigate a complaint process for an OTC class of hearing aid at two different governmental levels. That would be pretty confusing and retailers would be able to continue to sell.

My final concern is voiced as an audiologist and a consumer. I believe that the new manufac- -- that this class of hearing aid would bypass existing requirements and would not be substantially researched. I think that in the states we wouldn't be able to provide what we need to which was to help the consumer.

And I'm a consumer. I'm aging. My friends, my family, everybody's aging. I'd like to know that the FDA rules are actually helping us and that they're keeping everybody's hearing health safe. Thank you.

DR. EYDELMAN: Thank you very much. Mr. Malcolm Jewell, please?

MR. JEWELL: It looks a lot easier from out there looking up than it does up here looking out there. I'm Malcolm Jewell. I'm board certified in hearing instrument sciences. I'm also president of the Colorado Hearing Society. So I represent about 120 hearing aid providers who are all board certified. Almost two-thirds of them own their own private healthcare -- hearing

healthcare practices.

I'm also co-owner of Hearing Solutions in Louisville, Colorado, along with my wife Chris who's an audiologist and who just spoke.

Finally, I'm a member of the International Hearing Society and I am standing here today in support of the comments and positions that its representatives have shared with you in opposition of the PCAST proposals.

I know many of you have heard a variety of specific reasons why the PCAST proposals and recommendations either should be supported or they were ill-advised.

What Chris shared with you and what I'm about to share with you are not projections. They're not educated guesses. They're not studies. They are real-life experiences that directly demonstrate the significant pitfalls of the PCAST recommendations.

As Chris pointed out, the licensure road for hearing healthcare products in Colorado had a big pothole in it from the 1990s. And fixing that

pothole took hearing healthcare providers several years and took even longer for the general population to begin seeing honest improvement in their lives as a result of better hearing.

Because of the damage done the rebuilding process faced many obstacles, but none of them was bigger than overcoming public mistrust from two different perspectives.

First of all, anyone who sold hearing aids was only interested in money at best or they were sheer crooks at worse. And secondly, after a week or two if you're lucky hearing aids just don't work and what was promised doesn't happen.

In the years of rebuilding our profession one concern was paramount. That was how do we protect the consumer? In fact, initially Colorado not only developed laws and regulations governing our licensure, but they had separate regulations under our consumer protection statutes.

Our licensure laws went from nonexistent to among the toughest in the nation. Hearing aid

providers could only get their license by training for two years and passing the very rigorous NBCHIS exam.

Colorado's been determined to move from worst to first in protecting consumers and providing quality hearing healthcare. And we're very aware of how OTC aids and self-diagnosis and treatment would remove that protection and quality.

Let me give you a free couple of brief examples. I recently saw a patient that I'll call Joe, mostly because that's his name. Joe purchased a pair of hearing aids online on eBay and when he received them he was really excited so he tried them out. It was all he could do to jerk them out of his ears as quickly as possible because they were painfully loud.

Joe came to us to have his hearing aids adjusted, but unfortunately we couldn't do that. They were just too powerful so we couldn't accommodate his hearing loss.

So without consumer protection Joe lost

out in several ways. He didn't measure or understand the nature and extent of his hearing loss, he purchased hearing aids he couldn't use, and he damaged his hearing. It was only when he sought help from hearing healthcare professionals that Joe was able to safely and successfully solve his hearing problem. He ended up buying hearing aids that were appropriate for his hearing loss and that solved his most pressing hearing challenges and that fit his pocketbook.

I visited with another patient in an assisted living facility. Fred has worn hearing aids for several years and he's now in need of minor assistance in his day-to-day living, but Fred's going to be independent. So he still manages his own hearing needs.

However, he wasn't hearing very well and so the staff asked me to kind of investigate what was going on. I cleaned both of his hearing aids because they were clogged and that's very common any time you stick something in your ear. So that happens very frequently.

I also cleaned his left ear and that was about three-fourths occluded with ear wax. That happens frequently and that level of accumulation is common in the elderly population. I also very gently cleaned his right ear. It wasn't nearly as sore after I removed a size three-twelve battery that was encased in ear wax.

The point is that without professional guidance and assistance hearing systems simply breakdown.

Finally, a retired physician came to our office. He's active in rotary clubs and missions. And he had a pair of internet-purchased MD hearing aids. You've heard of MD aids earlier on an earlier presentation and we didn't coordinate our notes.

So he purchased these MD hearing aids and he was an M.D., too, so MD hearing aids are going to be okay, right? Wrong. They weren't okay. He needed help and the MD hearing aids he purchased on the internet failed.

Our evaluation showed that he had a mild

to moderate hearing loss and that the aids he bought from us ended up solving his problem and will contribute to his success in hearing for a long time to come.

He's just an example of someone determined to improve his hearing, but other people don't have the resources that he had. And they're finding out that hearing aids that are cheap, too good to be true hearing aids, are just that, too good to be true.

So are they going to give up potentially damaging their ability for a more rewarding life? Hearing aids are not just a cost price issue, they're a health issue.

I ask then that the FDA reject the two PCAST proposals and adopt the 2013 PSAP guidance. Thanks very much for your attention.

DR. EYDELMAN: Thank you very much. Ms. Sabrina McEwen, please?

MS. MCEWEN: Hi. My name is Sabrina McEwen. I'm from Towanda, Pennsylvania. I'm a wife and a mother and a patient and I'm consumer

so my story's going to be a little bit different than everything you've heard today.

I would like to start off by saying that I really think it's good that we're having this discussion. I really think it's good to discuss the benefits and the drawbacks of over-the-counter hearing aids. And I feel like I owe it to my family to be here today.

At first glance the answer to this question about whether the FDA should support over- the-counter hearing aids seems simple. Just like buying reading glasses at the drug store, this seems like it would be a good idea. Over-the-counter hearing aids like reading glasses should be a quick and affordable fix for a minor problem.

But when you look at individual people, people like myself, the intricate problems that can cause hearing loss, even very subtle hearing loss, the issue becomes more complex.

Take my case for example. In 2013 after years of gradual hearing loss which I didn't think

was so bad I finally went to see my hearing aid dispenser. I was a little nervous, but mostly excited that I was going to get hearing aids and be able to hear again.

After she tested my hearing and tested the hearing in my bone she looked at me with a lot of concern and said, "You have very profound hearing loss in one ear and I want you to go to an ENT to see what's causing it."

And it was because of that conversation that I didn't go to an ENT. I went straight to the emergency room and it was a good thing I did. When they did the CAT scan they found a huge mass in my brain which we later found out was a 6.4 centimeter acoustic neuroma. And I'll let that sink in for a second because 6. 4 centimeters is pretty big.

I was immediately admitted for surgery. In fact, my neurosurgeon was actually surprised that I was still alive because this tumor was pressing against my brain stem preventing the normal flow of fluid from the brain and the spinal

cord.

An acoustic neuroma is a rare benign tumor on the main nerve leading from the inner ear to the brain. The early symptoms can include unilateral hearing loss, tinnitus, and a sense of fullness in the ear which all should and can be recognized by your hearing professional. And I thank God every day that they were recognized by my hearing professional because I feel like she literally saved my life.

Although these types of tumors are uncommon and life threatening complications don't happen often, I'm probably the worst case scenario, it is of the utmost importance to see the professional and at least rule this out.

I hope that you can see how these current rules have helped save my life and that you're protecting people like me. If I had gone to my local drug store and been able to purchase over-the- counter hearing aids they wouldn't have resolved my problem. And I didn't think my hearing loss was severe. I'm pretty typical. But

I would have given up and I may not have sought further medical attention without her insistence.

Without a professional to talk to and to confide in and get tested by and FDA's rules and proposals were in place a few years ago I simply would not be standing here. My husband would not have a wife and my children would not have a mother. Thank you.

MS. EYDELMAN: Thank you very much for sharing your story. Mr. Emilio Alonso-Mendoza, please?

MR. ALONSO-MENDOZA: Good morning. My name is Emilio Alonso-Mendoza and I am the chief executive officer of the Alexander Graham Bell Association for the Deaf and Hard of Hearing.

AG Bell commends the us- -- the USA Food and Drug Administration for its efforts to balance patient safety while encouraging technological advancements and increase access to hearing technology. We appreciate the opportunity to provide these remarks.

AG Bell is the oldest and largest

organization promoting the use of listening and spoken language by children and adults who are deaf and hard of hearing. Our mission is to advance listening and spoken language for individuals who are deaf and hard of hearing.

We strive each and every day to ensure that every child and adult with hearing loss has the opportunity to listen and talk and thrive in the mainstream.

Our association membership is comprised of children and adults who have grown up with hearing loss, their families, and also the professionals who serve them.

One critical aspect of intervention for children with hearing loss is the use of hearing aid technology. Our concern is that stakeholders have largely focused on hearing loss as a condition focused on age. This overlooks a very important and vulnerable population of infants and children with hearing loss.

According to the Better Hearing Institute, there are more than 6 million people

between the ages of 18 and 44 with hearing loss. There are also at least 1.4 million children age 18 or younger with hearing loss.

Unlike adults who lose their hearing later in life and have a well-developed auditory memory for speech and sound, infants and children with hearing loss rely on access to well-fitted hearing technology to develop listening and spoken language skills.

Most experts agree that birth to three years is the essential age at which to develop spoken language. Without consistent and reliable access to sound a child's ability to spoken -- develop spoken language becomes severely limited.

Families of children with hearing loss face significant expenses to manage their condition. This is particular true for families with children who are deaf and hard of hearing who have chosen a spoken language outcome.

In addition to the cost of hearing aid there are costs associated with listening and spoken language therapies, communication access,

additional educational needs, and other accommodations.

The need for more affordable hearing technology was underscored in the AG Bell Family Needs Assessment Survey. The recent survey of 1,000 families noted that auditory verbal speech language therapy services, hearing aid purchases, and assisted listening devices were the most significant financial barriers for families in meeting the needs of their children.

Every week the AG Bell national office receives calls from families as well as individuals of all ages seeking help with the high cost of hearing aids. AG Bell has consistently advocated for legislative initiative at both federal and state level that would make hearing assistive technology more affordable.

AG Bell has developed a document that provides recommendations on over-the-counter hearing aids which is available on the AG Bell website. It is our position that hearing devices such as personal sound amplification products and

over-the- counter hearing aids should be more affordable.

AG Bell strongly recommends that hearing aids be obtained by children and adults who have grown up with their hearing loss only after comprehensive assessment and follow up by an audiologist.

It is particularly critical for children to be fitted with appropriate hearing technology. To ensure that children receive appropriate amplification AG Bell has developed a recommended protocol for audiology assessment and hearing aid evaluation and follow up for children.

In summary, we request that the FDA and other key stakeholders consider the needs of our youngest infant and children as well as adults who have grown up with hearing loss who rely on hearing technology for the ongoing development of listening and spoken language.

Both children and adults need audiology care prior to receiving hearing technology to ensure that the technology they select is

appropriate and well-fitted and that their hearing loss and any related medical conditions have been properly diagnosed.

We hope that the future brings exciting innovations and expanded access to hearing assistive technology. And that our children and adults receive the care they need to benefit from these advances. Thank you very much.

MS. EYDELMAN: Thank you. Now I would like to ask Mr. Andy Bopp to come up to the podium. And I believe he will be reading comments on behalf of Dr. Masak- -- Mr. Masaki Ikeda.

MR. BOPP: Thank you. As you said, my name is Andy Bopp and I'm reading -- going to read verbatim for Masaki Ikeda who could not be here due to travel restrictions coming from Japan. Could not make the trip.

"My name is Masaki Ikeda. I have a degree in international business and I have worked for more than ten years for Starkey in the U.S., Japan, and Asia-Pacific markets. I now work for Starkey as an international training manager based

in Yokohama, Japan.

Since the United States is considering proposals that include over-the-counter hearing aids and marketing PSAPs for hearing loss, it is important that you take the Japanese experience into account.

Professional service is the essential element to successful treatment of hearing loss. We're working to enhance professional service in Japan to improve our disappointing hearing aid adoption and satisfaction rates. It would be a mistake for the U.S. to adopt key elements of the Japanese model.

Do-it-yourself hearing aid solutions have not benefitted Japanese people with hearing loss. There are 14 million people with hearing loss in Japan out of 127 million people. This represents an 11 percent rate which is similar to the U.S. and other countries.

Government reimbursement is available to some people, but only those with profound or severe hearing loss at more than 70 dBs in both

ears. It does not cover the full cost of the hearing aid and services. Those with mild to moderate hearing loss have no coverage generally.

Hearing aids Khol Khal Ke are widely available in Japan including over-the-counter devices. There are also no restrictions on promoting PSAPs Su On Ke (phonetic) for hearing loss.

Access is not an issue. OTC hearing aids are sold in over 7,500 shops. This translates to there being one hearing aid shop for every 1,800 people with hearing loss in Japan. This does not count mail order or internet sales.

Only 62 percent of hearing aids are sold by hearing aid professionals at hearing aid centers or at hospitals and clinics. In addition, 14 percent of hearing aids are sold at optical stores and 19 percent are sold through the internet or via mail order with no professional service.

Sadly, the hearing aid satisfaction rates in Japan are poor in comparison to Europe

and America. Our satisfaction rate is only 39 percent compared to 81 percent in America and similar rates in Europe.

It is no surprise, then, that our adoption rate is only 13.5 percent compared to 30 percent in the U.S. and higher rates in Europe where most insur- -- more insurance coverage is available. It is commonly understood in Japan that our low satisfaction rates are directly related to our low hearing aid adoption rates.

There is less professional involvement in Japan and consumers often have problems as you can see here. Some of these problems can be expected when a consumer has no professional help with testing or fitting hearing aids.

Binaural fitting rates are much lower in Japan. Sometimes people purchase only one device since they are not given advice on the important of using two devices if needed. Here we see how that impacts on satisfaction rates for people with hearing loss. It is important to use two hearing aids if needed.

The result of this do-it-yourself approach is often poor fittings. This leads to poor satisfaction. There are efforts underway to increase the number of hearing professionals and enhance professionalism in Japan. This includes efforts by the Japan Hearing Instrument Dispensers Association to promote certification. 3,000 dispensers have received a certificate so far. The effort continues.

Japanese hearing aid technology is similar to what is available in America and Europe; however, there is much consumer confusion between PSAPs and genuine hearing aids.

Prices are also quite low in comparison, as well, which one would expect given the minimal level of professional service in Japan. Yet the low cost does not increase adoption.

Many of the reasons people do not buy hearing aids relate to issues that professionals can easily address. We wish to bring more professionals and involve physicians to a greater extent in addressing hearing loss in Japan.

It is important to compare existing models of hearing aid access. In Europe there are high levels of coverage and professional service. Europe has solid satisfaction rates and the best adoption rates.

In America there are low levels of coverage, but high levels of professional service. American had solid satisfaction rates and middling adopting rates.

We in Japan combined low levels of coverage with less professional involvement so it is no shock that we have the worst satisfaction and adoption rates.

Before the U.S. takes steps that will lesson professional involvement it should understand the Japanese experience. Access does not equal adoption or a good public health outcome for persons with hearing loss."

DR. EYDELMAN: Thank you very much. Ms. Donna Sorkin, please?

MS. SORKIN: I'm Donna Sorkin. I'm the executive director of the American Cochlear

Implant Alliance. I grew up with hearing loss in my family. My father was hard of hearing and more hearing aids throughout his adult life which helped him in quiet and at close range from speakers. But he struggled to understand speech in noise, speakers at a distance, and using the telephone.

My father retired on a medical disability hearing loss in 1973 at age 52 as he could no longer perform his job. He had no accommodations as this was prior to the Americans with Disability Act and changes in societal perspectives that now emphasize providing such assistance.

His mother, my grandmother, was profoundly deaf and she derived even less benefit from early hearing aids. My sister and I both inherited hearing loss. With the dramatic improvements in hearing aids that have occurred over the past 20 years after my father's death, my sister, whose hearing loss is more severe than my father's, functions well with amplification and

other accommodations and she had a long career as a medical research scientist.

My own hearing loss progressed rapidly. When I no longer benefit from hearing aids my audiologist encouraged me to pursue a cochlear implant. Throughout my hearing loss journey my audiologist also helped me in knowing what other technologies and solutions might improve my ability to live well with hearing loss. She helped me to learn that hearing in various settings wasn't just about purchasing a hearing aid even when my hearing loss was in the moderate range.

My son, who served our country as an infantry officer in the Marine Corps, developed tinnitus and a decline in his mild hearing loss during his military service. And he has been guided by a competent hearing care professional.

I migrated to this field because of my desire to improve the quality of hearing healthcare and to increase awareness about not only traditional amplification, but also the range

of technologies that can help people with different kinds of hearing loss.

I served as Executive Director of Hearing Loss Association of America and AG Bell Association and then I served as 11 years as Vice President for Consumer Affairs at Cochlear Americas, a manufacturer of implantable hearing devices.

Much of my work revolved around gaining insurance coverage for BAHA, the bone anchored auditory device. Gaining insurance coverage was and remains a huge challenge. We work to maintain access to care in the face of resistance by insurance providers to recognize this hearing device and even cochlear implants within the hearing healthcare system.

Three and a half years ago I was appointed Executive Director of the American Cochlear Implant Alliance, a new non-profit organization, which is focused on access to care.

The PCAST report mentions that its proposed changes would disrupt current business

practices for hearing aid dispensing. This is true. Not only would existing coverage of hearing aids under private plans probably disappear, it could also complicate existing insurance coverage for other hearing devices such as the bone anchored auditory implant or BAHA, which is indicated for people with mild to moderate hearing loss.

Now to the point of my comments. We're concerned about this proposal which would consider this new class of amplifiers as consumer electronic devices because it would, one, denigrate the impact of hearing loss for people with mild to moderate hearing loss for whom the services of a trained hearing care professional is not needed nor important according to PCAST and also the characterization of older adults not needing hearing healthcare.

It could lead people to believe that the proposed new class of amplifiers will alone fix a hearing problem. Three, it could negatively affect insurance for hearing aids as it exists now

and other devices such as the bone anchored hearing aid which includes those in the mild to moderate range.

And fourth and most importantly, it will further advance the unfortunate view among many in our society of hearing loss as not being a health issue nor being important enough to warrant care by hearing care professionals.

There are comparisons made in the PCAST report between hearing aids and over-the-counter eyeglasses or readers that one purchases without a prescription at drug stores, gift shops, airports, or in museum shops which is where I bought these lovely red glasses.

Correcting close range vision loss with readers is not the same as correcting hearing loss. We these I see the page much as I did when I was 25. It is unusual that any hearing aid, even the most high-tech -- high-tech technology can fully restore hearing for someone with moderate hearing loss.

Few people have flat audiograms and

hearing technology is considerably more complex than a pair of readers. Most of us are unable to conduct the kinds of analyses that have been discussed by speakers today. And people with hearing loss, particularly older people, need the guidance of a hearing care professional.

Though we certainly agree that the cost of hearing aids is a significant problem, it deserves more attention than it's received to date. We have concerns about an approach that changes the definition of hearing aids from a device that requires diagnosis and fitting by trained professionals to that of a consumer electronics product that one purchases much like a cell phone.

We also degree -- disagree that the level of one's hearing loss determines the need for diagnosis, proper fitting based on an audiogram, and other testing, and professional guidance.

Hearing loss is a health issue, though it's often treated as something entirely

different. This proposal to deregulate hearing aids will exacerbate this problem and could interfere with insurance coverage of implanted medical devices as well as existing coverage for hearing aids.

In our opinion, this is a big downside to a proposal that seems not to have been considered. We need to address the unintended consequences of deregulation.

I'd like to end with a short story. I've often discussed the challenges our family has with hearing healthcare for my 92-year-old mother who lives in a skilled nursing facility in Washington, D.C. In fact, the only five star facility in the city.

My mom has a moderate hearing loss which means she's someone who, based on the PCAST report, doesn't need the services of an audiologist. With her hearing aids on she's able to converse with us and with others in the facility where she lives and she's able to stay connected with this technology that has really

made a dramatic difference.

The problem is keeping the hearing aids on her. We went to visit her recently on a Sunday morning at 11:20 in the morning to find her without her hearing aids on. And this actually happens a lot.

She immediately mentioned that she couldn't hear me because she didn't have her hearing aids on. I went to the nurses' station to pick them up and asked why they had not put them on her. She had gone to breakfast and morning activities without being able to hear and engage with other residents.

The nurse stated, "We forgot."

So I responded, "Did you forget to dispense her medications today?" "Of course not," she said. The implication being that hearing aids are not all that important and are not part of my mother's healthcare.

Before jumping on the deregulation wagon let's consider what this proposal could do to further degrade our society's view of hearing

loss as not being a critical element of healthcare.

The PCAST proposal alarms us not only for what it could do to services for people who need hearing aids, but also for what it could do to the larger hearing healthcare system including existing insurance coverage. Thank you.

DR. EYDELMAN: Thank you very much. Ms. Elisa Cimento, please?

MS. CIMENTO: Hi. My name is Elisa Cimento. I'm currently an intern at HIA, but I also have moderate hearing loss as a 22-year-old adult. And I'll be speaking about my experiences personally and not representing HIA.

The biggest surprise I think when I transitioned to college was exactly how many people started asking me questions about my hearing loss. More specifically, not people who were my age, but my 50 to 70-year-old professors who caught onto the fact that I wore hearing aids and suddenly were very excited to ask me a lot of questions.

I got cornered a lot of the times in office hours or after class asking do you wear hearing aids every day, do you like wearing hearing aids, like how do you do this, what do I do, what's your brand name, all the above.

And talking to them a lot of them didn't really know how to deal with their hearing aids and they would just say, "Oh, do you know why I can't do this or do you know how I can fix this problem or what do you know about this?"

And my general response to them would always be, "Well, did you go back to your audiologist? Have you talked to anyone else about this besides me?"

And they would say no. And so my usual suggestion would be, well, why don't you give your audiologist a call and, you know, make an appointment and see what they have to say.

And so they would do that and then a couple weeks later I'd run into one of them in hall and they'd be real excited and they'd be like, "Oh, my God. I just talked to them and this

was like really cool and we changed the programming ," or one guy was like, "Yeah. We changed brands. I really, really like this brand now. Like the old brand just wasn't doing it for me but now this is great and like I can hear my wife all the time and she's not mad at me."

And then I ran into his wife two days later and she was like, "You're my favorite. He finally wears his hearing aid. Like he understands what I'm saying."

And but again like these were all educated adults who didn't know what to do with their hearing aids and all of them had advanced degrees, all of them you would think would know, you know, put your battery in, test it to make sure it's working, make sure there's no ear wax in the little ear canal. But no, they didn't think to do that. And you needed training to go on to do that.

And talking to my audiologist she said that's a common problem that she has with a lot of her patients. They'll come in and most people

just didn't change the battery and they'll come in saying their hearing aid's broken. And she like, no, like you just need to change the battery every two weeks, every week. And then she'll go and try to give the hearing aids to them or she'll set up a weekly appointment so they come in.

And she's like I need them to understand that this is the process between the two of us and that they need to take initiative for their own health and that they can, you know, do this on their own. But, again, none of these people could just do this intuitively. Like it had to be training for them.

And in my case I was lucky enough that I got this training as a six year old instead of being a 50-something year old, but and that's the case for a lot of my other friends who have hearing aids in their 20s. But a lot of people just don't have it and like you need practice. And, okay, you can buy the hearing aid online, but you're not going to know what to do with it so you might as well have someone teach you for what to

do with it.

So in my general perspective like audiology, itself, has been very helpful. It's been a teamwork. I've been made to understand that it's my health and I need to be an initiative for my health. But I can't do it on my own.

And if you talk to any of my 22-year-old friends, the only ones who really know what they're talking about are the ones who are coincidentally studying to be audiologists. So I can call them all I want, but they're not licensed yet so I should probably call my actual audiologist.

So I would not necessarily say that I'm in firm support of, you know, just selling the hearing aids over the internet and grabbing them and just saying it's a free for all because most of my experience has been people not knowing what to do for the free fall.

I mean, obviously as a consumer I would like hearing aids to be cheaper, but like everything in this world is expensive so why knit

pick this specific thing if it's a benefit for my health then it may have taken me a while, but I do understand that. And I think in general it would be good to keep the hearing healthcare practice as a partnership between you and someone else so you can continue to take care of yourself.

DR. EYDELMAN: Thank you very much. Ms. Darleen Wilson?

MS. WILSON: Hi. I'm Darleen Wilson. I am an independent researcher. I'm very happy to be here today. Alissa, I love your advocacy.

Because hearing is a defining issue for millions of Americans, millions of people, and certainly for me personally the topic I propose to address is how adopting PCAST recommendations is good for patients and audiologists and the hearing aid industry overall.

See, I think there's a clicker here. There we go. So just to give you a little bit of context of what informs this opinion, I'm a musician. I've been an intent listener all of my life. My first career was in audio as a recording

engineer and a record producer.

Currently I'm a user/researcher probing the experience of hearing and hearing loss. I've been wearing hearing aids for ten years top-of-the- line models. This is my third pair. As much as they've helped and as good as they are there's a gap between what they deliver and what my audio background and listening habits suggest is possible.

So I went back to school and got a Master's in human factors and information design and I'm now immersed in research. I'm exploring what I call the ecology of hearing, investigating multiple perspectives, interviewing individuals with hearing loss, audiologists, sound designers, engineers, and auditory scientists.

That's a topic. Today's topic is one I've thought a lot about. My research indicates that the top two reasons people resist getting hearing aids are, number one, they're really expensive; number two, people don't want to be perceived as old.

PCAST recommendations are a good start, in my opinion, to combat resistance for financial reasons. The report -- as for the association with age the report's so heavily focused on the needs of our aging population it almost reinforces the association.

Even so it's my feeling that once people have easier, more affordable access, assistive hearing technologies will be more widely adopted and attitudes about who's wearing them and why will change.

There used to be a saying perpetrated as fact that guys don't made passes at girls that wear glasses. Now glasses are a fashion statement. Now I'm not comparing glasses to hearing aids or eyes to ears. I'm comparing the perception and the stigma and I think we need to do everything we can to make hearing much more of a talking -- talking points in our society. It's critical that we make the shift.

Medically hearing loss is categorized as a communication disorder. When you hear you can

engage in relationships and the world around you. What happens when the neuropathways associated with hearing are not used? Misunderstandings, isolation, cognitive decline.

If we can prevent these life limiting consequences, why wouldn't we? Let's see, there's a button here.

Audiologists. So the audiologists I've interviewed tend to be in the extremes of pro or con of the PCAST recommendations. One young audiologist volunteered his concern about the future of his profession due to the, quote, "the proliferation of personal sound amplification products." He was concerned about these entering the marketplace.

Interestingly the audiologist who I interviewed who is the most fervent advocate for these devices is someone who's been practices for 30 years. A demographic you might not -- you might think would be most resistant to change.

My own audiologist has been an invaluable partner in my search for a hearing aid

that will remove the great divide between me and sonic pleasure. I'd like to see hearing tests mandated, not PCAST's recommendations denied.

I believe the role of audiologists will become more important, not less, as hearing gets more attention in our noisy culture.

According to the -- according to the Journal of the American Medical Association, one in five people who need hearing aids wear them. Clearly there's a huge opportunity for an industry that could be poised to meet the demands of such a market.

With no indication of how they might better serve the urgent need the Hearing Industries Association issued a white paper strongly disagreeing with the PCAST recommendations.

Again, I would suggest that hearing tests be mandated if we're looking for change. I would suggest that rather than looking for ways to resist technological change, which, face it, is going to happen anyway, the hearing industry

should champion advances that enable and encourage users to be proactive in addressing their hearing challenges.

I'm convinced that by embracing low-end solutions that can help individuals navigate their world that will not preclude middle or high-end markets. Indeed, low end affordable products can establish a glide path to more sophisticated solutions.

So for all these reasons I whole heartedly support the recommendations made by the President's Council. I appreciate that the FDA is holding this -- holding this conference today. Let's advance the industry and the practice and give all hearing compromised individuals choice and support. Let's start by adopting the PCAST recommendations. Thank you for your attention and your consideration. I may be hard of hearing, but I can hear stomachs grumbling so thank you.

DR. EYDELMAN: Thank you very much. This concludes the comments from the individuals who requested to speak prior to the final date

published in the Federal Register.

We have a few minutes so I would like to ask if there's anybody in the audience that wishes to address the audience at this time. If so, please come forward to the podium, state your name and affiliation. You will be given five minutes to provide your comments. Go ahead, sir.

MR. KINSBERGEN: My name is Jaques Kinsbergen. I'm the C- --

DR. EYDELMAN: Come up to the podium.

MR. KINSBERGEN: My name is Jaques Kinsbergen. I'm the CEO for Jacoti. It's a European company focusing to bring a transhearing technology reach a broad population.

And this is a hearing aid. This is a CE approved hearing aid and (indiscernible).

Oh, sorry. This is an -- this is a hearing aid. This is a CE approved hearing aid and FDA hearing aid. Including a self-test, a calibrated self-test for hear -- calibrated self-test for hearing and it's software connected.

That means that you can do your test

locally in a silent environment, a calibrated test. And the data will be also going through the server. Your audiologist can get access to your data in the server, you as a user can get access to your data in the server, and the audiologist can also if he or she want adopt the data in the server.

Included in the system we included audio streaming technology for the complex listening situations like this. That means we have a consumer-based audio streaming technology, we have software, you have mobile phone, you have a standard wireless router, and you stream CD quality audio into a room.

This with latency of around 60 milliseconds. So that means that can bring audio with no noise into -- into a room, into the mobile phone of a listener and you can connect that to your ears.

That can be connected to your softer hearing aid. That means that in complex listening situations you can use purely your mobile phone as

an assistive listening device compensated for your hearing loss.

I just want to -- this is what I wanted to bring you to just tell you that probably part of the discussions is passing the reality of today. The reality of today is starting this CE approved device and an FDA registered device.

So it's possible for a very small company to comply with regulations. We are -- we have full quality management system in house. That means that we are fully comply like normal hearing or a normal medical device companies with the regulations.

We are classified as a Class II aid device in Europe. That means that this is close to III like implants. So deregulation I don't know. We are chos- -- we have chosen to comply because we believe as a global company that we should comply. I think we cannot focus on one market which would deregulate this technology. We would focus on the world market with, yeah, who is only looking for more complications in the

regulations.

We -- just for instance a change in the regulations in Europe for medical devices that means that technologies, medical devices which are on the edge of being medical -- medical technology are not. They would be classified as medical devices.

So that's all that I want -- want to tell you and want to show you. The application is on the App store so it's not something in the science lab. Everything what you -- what I'm talking about you can download. It's on Jacoti. That's the company name. Thank you very much.

DR. EYDELMAN: Thank you. I believe there's somebody in the front row. Please proceed to the podium.

MS. CHANG: I know everyone is dying to go to lunch, but I'll keep this short. My name is Wendy Chang and I'm actually a Federal employee in this agency. But I'm not really here as an employee today so much as a consumer.

I've used hearing aids for most of my

life. And here I lost the remainder of my hearing about 27 years ago and now I have bilateral cochlear implants.

I want to thank the CDRH staff here who put this together because it's been an eye opener. I've learned so much just by listening to you all.

And I should say that I also run a small support group in this agency for individuals with hearing loss. And occasionally I'm always thinking who can I bring as a speaker for a monthly webinar we hold? And so, of course, all the discussion I've heard today has just been like, oh, this might be person I could talk to.

So anyway, if you're interested in shar-- having the time to share some about your -- of your company's offering or whatever, just come see me. I'll be here for most of today and through this afternoon. Thank you.

MS. EYDELMAN: This concludes the open public session. I'd like to thank all of the speakers for their comments.

At this time we will break for lunch.

We've allotted an hour for lunch so please return here no later than 2:10.

When you return before you run I would like for the 12 of our invited speakers to please come up to the front and take a seat at the panel table for the duration of the afternoon.

Now you can go to lunch. Thank you.

(Whereupon, a brief recess was taken at 1:00 p.m., and resumed at 2:10 p.m.)

DR. NANDKUMAR: Okay. Good afternoon. We'll now begin the invited speaker session. And I think there is no signal on this yet. We'll try to get this up as soon as we can.

Yes. Okay. Thank you. And, okay, I would like to once again thank all of our public speakers for their contributions to our workshop this morning. Your talks were very informative. Thank you.

I would like to also mention that Dr. Randy Brockman who's the Office of Device Evaluation's Chief Medical Officer and Acting Clinical Deputy Director will be moderating the

question and answer sessions for our invited speaker sessions this afternoon. Thank you for being here, Dr. Brockman.

And now I would like to introduce our first invited speaker session on the topic of hearing aid access. The questions that you see -- that you saw that were up there were all -- were sent to all the invited speakers to help -- to aid them. There are questions like this for each of the three sessions and they were sent to them to aid their presentations for this afternoon.

We will have four ten-minute presentations followed by a 20-minute moderated question and answer session. And all 12 panelists are invited to participate in the moderated Q and A.

(Brief pause). Okay. Great. We apologize for the delay, but I think we got it to work. So thank you for your patience.

And now we'll have our first speaker come up, Margaret Wallhagen of the Hearing Loss Association.

DR. WALLHAGEN: Well, good afternoon. And I want to thank the FDA for the opportunity to participate in this very important discussion with obviously a wide range of input and different viewpoints.

First of all, in terms of my disclosures I really have no financial disclosures. And the slide outlines the unpaid board memberships that I have. And I'm currently the Chair of the Board of Directors for -- or board of trustees for the HLAA.

I want to first of all say that as you probably know HLAA's a consumer-oriented organization with a mission to open the world of communication to persons with hearing loss through a variety of activities.

As such, a prime focus of our organization is on accessibility and affordability of hearing healthcare including hearing aids and other assistive devices, but also certainly consumer protection. It is from this perspective that I will be addressing the questions that we

were asked to respond to.

The first question was: What are the barriers to hearing aid use? And you will see some repetition in the slides because the questions really do overlap. And access for the purposes of this question I'm viewing as composed of two sections. For access into the system and then to appropriate -- and then access within the system in terms of appropriate care and services.

Now these obviously overlap, but it may be useful heuristically to consider where an intervention might most appropriately be used. I will not be addressing the psychosocial determinants of preventing or access to hearing healthcare.

So access into the system you've heard a lot about cost. And certainly one of the things we're very, very concerned about is the cost of hearing healthcare and the lack of insurance company coverage.

Most of you know that Medicare does not cover hearing aids or any other kind of hearing

healthcare services. It's a statutorial limitation.

Medicade unfortunately also has very uneven coverage across the states. Most don't cover hearing aids, but if they do they don't cover it for adults but mainly focus on children.

There's also the need for physician clearance. And I'm not talking about ENT physicians, but more primary care physicians here. But primary care physicians actually know fairly little about hearing healthcare and the evaluation of hearing needs and there's a lack of screenings.

So even if you don't have the referrals and so forth from the standpoint of accessibility or the referral option, most hearing healthcare practitioners do not refer or do not check individuals' hearing even if you consider this standard of care. So that they don't -- about 20 percent may screen for hearing loss. And there's also a limited number of hearing healthcare professionals.

So then when we turn a little bit more

to access within the system there's the bundled payment system and the lack of cost transparency. This really makes it seem more expensive to the person with hearing loss because they come in and see very, very large prices and don't understand that that includes many times the services, as well.

There are return fees. This is not universal. But, again, the return fees can be detrimental in terms of individuals being afraid to try out the hearing aid because they know that they have to pay a significant amount to just take it back and say it's not working.

There's inconsistent consumer focus care or use of best practices and insufficient consumer education regarding hearing aids as well as the other options that are needed, including aural rehab.

And I say inconsistent because certainly that's not universal, but it's also not uncommon for the kinds of guidance that we've been talking about this morning to not occur for persons who go

to professional service. So they're not getting the information they need for effective use of hearing healthcare devices.

And then there's also partly based on this a distrust of this system and a belief that hearing healthcare providers are focusing on selling hearing aids. That's not benefitted from some of the ads that you see in the papers.

So the next questions was: How can hearing aid access be improved in the U.S.?

Well, it sort of gets at some of the points that I've just made. One is certainly there needs to be further education of the primary care practitioner and the promotion of hearing screening in primary care.

There should be consideration of maybe eliminating the referral from the physician before the person can go to see the audiologist. Data suggests -- has been brought up before -- that the waiver is the most common use now. So people are not getting screened beforehand and are referred back to the primary care practitioner if

they need medical care.

We do believe and we strongly support Medicare coverage of hearing aids and aural -- especially aural rehabilitation to be included in that because they need to know how to use the hearing aids if they get them.

We think there should be consistent Medicade benefits across the state that includes adults and should be also obtain uniform coverage through the Affordable Care Act.

We do believe that unbundling charges to promote transparency would be helpful to the consumer in terms of their ability to really evaluate the cost. And that will be needed if it's consider -- if it's considered that you take your audiogram and go somewhere else for tr- -- for care. You'll need to know the various kinds of costs that are involved in actually getting the care that you need beyond the hearing aid, itself.

And then I think we need to incentivize the incorporation of aural rehab into all services so people do get the adequate information they

need to actually use the hearing aids effectively.

Additionally, we are supportive of the allowing access to a range of venues including consideration of the classification of over-the-counter products that were recommended by PCAST.

As you probably know, HLAA did come out in support of the PCAST report, but we also strongly recommend and support careful consideration of appropriate regulations or standards of the products with clear labeling so that the consumer is empowered and knows what they're buying and knows the limitations and what's possible.

And we do certainly feel that there needs to be additional discussion around these issues partly related to some of the confusion around the various systems that are out there that I'll mention briefly in a minute.

And we'd like to see certainly websites or other venues that allow easy comparison of the options. I think it was brought up this morning that very frequently people do not have the

capacity to compare across hearing aids or other kinds of things in terms of their usability or the best use for them in a particular situation especially with a range of hearing loss that we see right now across the whole lifespan. Not just the older adults, but the 18 year old to 105.

Then we were asked also to think about the consumer perspective which often certainly echoes the comments that I made before. The consumer is concerned about the cost and would like to see lower cost with unbundling and more transparencies of cost.

The easier access and less system complexity. The system right now is extremely complex with its multiple entry points and types of professionals that they may need to go and see.

They would like to see insurance coverage that's sort of universal and not spotty. And consumer focused, consumer driven care. Individualized care that allows them to see the options available.

We've seen persons with mild hearing aid

-- hearing loss to be turned away from audiologists and say, well, you don't need them now. Come back later. And that may not serve them well in terms of some of the issues that were brought up around brain changes that occur with hearing loss.

And we need a system for consumer reporting of problems that's really clear to the prac- -- to the consumer so that he or she can go to someplace and be very able to report complaints of whatever system that they get or whatever device that they end up using.

And there also needs to be some differentiating -- differentiation between the long- term hearing aid user and the new user because sometimes a person who has very stable hearing loss is put through some of the same processes that the person who is a new user goes through. And so there needs to be some consideration of the various ways in which a very informed person can maybe use the system in a more affordable way as well as the new user can get

into that, as well.

And then do the FDA regulations create barriers?

Again, this repeats much of what I've said, but the preevaluation from an MD prior to entry, PSAPs are not clearly defined with newer wearables and hearables coming out on the market.

So that we really -- this is complexity of interpreting the need or how do we valuate these systems. So we need further discussion on where the regulations are and where the boundaries of these various systems are for people to be able to understand them.

We now have two classifications -- Class I and Class II. And we're not totally clear on how the wireless -- when wireless capacity is so available on other devices what the rationale is in some ways and that can increase cost. So maybe more specifics about that. And then a sort of separate regulations. There are state regulations that complicate the system.

So in summary, we believe in broad

access to across multiple entry sites, accessible venues to meet the range of hearing needs with clear labeling to empower the consumer and consumer-focused care, insurance coverage and aural rehab, unbundling, systems for consumers to report problems.

And we do look to the recommendations from the National Academies of Science Committee on further guiding us how to best promote access to appropriately vetted products at reasonable costs. So thank you. I think I just ran out of time.

DR. NANDKUMAR: Okay. Thank you, Dr. Wallhagen.

Next speaker is Alicia Spoor from Academy of Doctors of Audiology.

DR. SPOOR: Thank you. Again, my name's Alicia Spoor and I'm here representing the Academy of Doctors of Audiology.

Before we get started I do want to go over a couple disclosures. Mainly that I am the owner of my own private practice, Designer

Audiology. And that's my financial tie.

So first of all I want to say thank you to the FDA for inviting us to speak on this important dialog as we are very interested in the business and clinical audiological practices at ADA.

So for today's discussion I want to go over a couple terminology pieces that you're going to hear in the presentation just to make sure we're all on the same page.

Any time I talk about a consumer patient I am referring exclusively to the adult population. Hearing aids are referenced as a Class I device which are exempt from premarket review and clearances. I understand that in this limited time this is a very high-level presentation and that supplemental materials will be provided in our written comments. And I want to make sure that the questions that we provide answers to are specific to that FDA.

So first of all what are the biggest barriers to care? And we really see it as three

different areas. One is awareness, the second is cost and affordability, and the third is an unclear pathway to care.

So when we talk about awareness patients and consumers are really unaware of the benefits of protecting their hearing. Additionally, the importance of treating and optimizing any type of hearing loss is not aware to them over the course of their lifetime. They're unaware of the associated co-morbidities that go with hearing loss and the efficacy and treatment that comes from a device in a rehabilitation process to ensure best outcomes.

And this awareness really extends beyond the patient. Also extends into the healthcare system as many physicians and providers aren't knowledgeable and don't screen when it comes to hearing.

We know that cost and affordability is the irrefutable barrier as there have been seven agencies that have addressed this over the last couple years and there are at least four pieces of

legislation in Congress that help relate to the device and the cost of associated treatment.

Additionally, there's an unclear pathway to care. So this can best be summarized by a patient who's trying to drink from a spigot and walk through a maze. And I tried this and it doesn't work.

There's an ill-defined professional rule from physicians, ENTs, hearing aid dispensers, audiologists. There's state and Federal regulations including the FDA's that are confusing to patients and to providers and they're often contradictory by other rules and regulations.

And there are technologies. And those technologies come from both the devices and the online and telephonic testing options that are available.

So I want to take this from a consumer perspective. I'd like to introduce you to Ruby. Ruby's a 66-year-old female and she's thinking, well, I have a little bit of hearing loss. So who's going to help me? My primary care, my

audiologist, my dispenser, my ENT, my internet? I'll just ask Siri. Siri knows everything.

But once I decide now I need to figure out treatments. Do I do a hearing aid, do I do a hearing aid as a PSAP, do I do a PSAP? How about a hearable ALD, how about a phone app?

Now I figured out who I'm going to see and my device, but depending on where I go I might have to do a medical evaluation. I'll just waive it. And then most devices aren't covered by insurance and they're associated costs so I don't quite know what to do.

So with all that are any of your surprised that patients wait seven years to obtain devices? Are they confused? Are they confused? They are frustrated? Are they tired? I don't know, but maybe they're just trying to figure out the system that's in place.

So when it comes to FDA regulations, we know that FDA has regulations to create barriers to hearing aid access and they were designed to do just that. The FDA seeks to ensure that barriers

are in place to keep patients from avoidable harm.

In 1977 when the rules and regulations related to hearing aid dispensing were enacted the landscape was dramatically different. Technology and the profession of audiology have significantly changed since that time and the regulations have not kept pace. Therefore, the FDA regulations currently pose unnecessary and harmful barriers for access to treatment and outcomes of hearing loss.

When it comes to the evaluation we recommend eliminating the medical clearance required for a hearing aid purchase. There's no evidence that this waiver achieves its stated purpose of identifying medical conditions and protecting the public.

Consistent with the tenth amendment, the FDA is intruding in clinical practices in an area it's not intended in its purview. Audiology is a clinical doctoring profession and we are trained to identify and refer for underlying medical conditions. The medical evaluation is no longer

necessary.

The FDA requirement is anticompetitive and it's forcing patients into a narrow set of providers that are often not in the best position to provide a one-stop shop care 90 percent of the time. At a minimum the amendment needs to be changed to allow medical or an audiologic evaluation. The rules today are anachronistic and void of virtue in their stated intention.

The cost to the patient and to the society of this is tremendous in duplicated services. In the interest of evidence-based practice and healthcare the FDA must eliminate the medical waiver and amend it to include audiologic evaluation at a very minimum.

The medical clearance because of that it's much easier to get a hearing aid now through the internet than it is to go through a provider. And the Missouri courts in 2006 confirmed this.

The FDA regulations were developed in 1977 when audiologists started dispensing hearing aids. And as we heard earlier, the medical

evaluation was necessary due to that door-to-door salesman that were praying on the elderly.

In 1993 testifying by Dr. David Kessler, then the FDA director, reported that the waiver was used far more often than intended and it was not fulfilling its original mission. He also noted that the audiologic evaluation at that time would suffice and state licensure ensures competency and consistent training.

The FDA took meaningful steps towards changing the rules in the mid to late 1990s and you need to go back and finish that work.

Eliminating the waiver would improve access and reduce cost. Did I lose my slides? I'm really sorry. There you go.

Finally, eliminating the waiver would improve access and reduce cost. The evidence shows that 90 percent of adults with hearing loss have a sensory neural hearing loss that's not due to medically treatable conditions.

Hearing loss is identified through an audiologic diagnostic testing and not a medical

evaluation. Eliminating the requirement would address both affordability and foster direct pathways to care.

So I just want to review the FDA hearing aid definition and the identification and classification asthis is going to relate to our second topic and that's the intended use piece.

The FDA relies on intended use rather than technical features of the device to determine if it's regulated or not. Intended device includes the labeling, the manufacturer statements, the marketing, and the knowledge of how the device is to be used, but not its actual use including potential off label uses.

It's hard to imagine that any of the prosthetic devices, surgical tools, or other Class I devices are being used recreationally for non-medical purposes, drugs being aside.

Hearing aids are a bright contrast from other medical devices and they are technologies that are similar and sometimes identical to PSAPs and hearables that are being used for recreational

use. Counter to the FDA guidance, many PSAP manufacturers are actively marketing their products for the purpose of treating hearing loss.

Additionally, some of the new manufacturers register their devices as hearing aids, but they've chosen to market them as PSAPs because it's easier to get to the consumers.

We also want to allow transparency. Rather than turning a blind eye, the FDA should restructure the regulations to align with today's technologies and evidence-based practices. Allowing devices that are FDA registered and Class I should be sold direct to patients.

Ensuring output limiting for a mild to moderate hearing loss on these devices is essential and this will encourage manufacturers who meet the FDA requirements to register and allow them to market to the public so that they can make informed decisions about their treatment options.

Of course, there are risks that come with self-treatment, but these risks are already

being taken with limited or misinformation. The FDA has provided separate guidance on apps and wellness hearable technology. You can do the exact same thing with hearing technology.

Data today shows the risk of not treating hearing loss could be greater than self-treatment. And given the comorbidities of hearing loss and the benefits of amplification improving the quality of life and mitigating serious health issues, we recommend Class I hearing aids to consumers over the counter.

This would allow manufacturers to register, label, and then market devices appropriately. And these OTC and direct-to-consumer devices should be specifically labeled to include a very strong recommendation to seek a comprehensive audiologic evaluation for an audiologist and/or a physician prior to purchasing the device for hearing loss specifically if any warning signs of ear disease are present.

We recommend clear labeling of non-surgical air conduction hearing aids intended to

address hearing loss.

So the regulatory pathway is anything but straight and we know that over the last 40 years. This new area of rapid technology changes will continue and patients, providers, and regulators will be faced with more decisions and challenges. Don't make it more complicated than it needs to be to ensure safety, security, and efficacy.

Remove the medical clearance, allow low risk Class I devices to be sold over the counter and direct to consumer with a strong recommendation that patients seek proper evaluation and treatment.

With this you will create more transparency and an affordable pathway to safe and effective care. Thank you.

DR. NANDKUMAR: Thank you, Dr. Spoor.

The next speaker is Evelyn Cherow from Global Partners United.

MS. CHEROW: Good afternoon. It's a pleasure to be here. I thought we were supposed

to give our speeches and title so you'll see my bias from the beginning. Hearing Technology for Communication and Quality of Life Access.

Going to be speaking about U.S. global drivers, human centered systems design, and 21st century hearing aid device regulation.

I have no financial interest in the material that I'll be covering, but I want to admit -- and it gives away my age -- that I had the opportunity to testify at the hearings in 1976.

I was a pediatric audiologist at the National Demonstration School at Gallaudet University where I started the audiology and otolaryngology program and the diagnostic and support services unit. And so I spoke those -- at that time on direct access to audiologists for children's hearing healthcare.

Here I am. I don't expect to be here in another 40 years so I'm going to try to say everything I want to say for the rest of my life.

I was ASHA's Director of Audiology

Practice Policy from 1981 to 2001 and had the opportunity to meet with Commissioner Kessler at that time to talk about please, please let's revise these hearing aid regulations. And he was very receptive, but other tobacco industry things came up at that time and we never were able to move that forward.

I've also been involved with both the Centers for Disease Control and Prevention and NIH, the National Institute on Deafness and Other Communication Disorders in drafting the hearing chapter objectives for the U.S. Public Health Service, Healthy People 2010 and Hearing Healthcare Objectives. And after leaving ASHA I switched careers I thought and I went to Harvard Kennedy School and focused on international development and have been working primarily in disability policy and program development for low and middle resource countries so you will see my bias here today.

I won't go over the prelevance data. I

think we all know what it is and others are going to be covering it. But in answer to the first question what are the barriers, we've heard a lot of the barriers. And PCAST has offered their analysis of the barriers.

I was interviewed by the PCAST, several people from PCAST, back in July. And at that time I had some trouble with the recommendations I thought would be forthcoming. And somehow they recommended me to speak I guess in that context.

So we all know the patient considerations -- perceived need, cost benefit analysis for hearing healthcare and devices, and inadequate coverage.

The value of hearing screening and diagnostics has only improved to 23 percent. And I took a lot of this data from the MarkeTrak 9 report. Sound quality, clarity, cost effectiveness concerns, speech and noise, and patient understanding of hearing aid features.

But I think we need to look very carefully -- and some folks who spoke this morning

spoke about healthcare systems considerations. And while that is not necessarily the purview specifically of the FDA, I'm going to focus some of my recommendations there.

The regulations related to gatekeeper for safety, rationale, and process which my colleague just discussed. The fragmented public health policy implementation. And we know that primary prevention and secondary prevention are poorly funded in our country and in other countries.

The currency and accuracies of physician's knowledge, which was also just covered, is questionable about the fields of rehabilitation. And in our instance here healthcare for people with hearing loss or at risk for hearing loss. There just isn't current knowledge of hearing aid advances. And so the consults with patients are questionable and the lack of referral to hearing care professionals.

And then we have in our own country specialty personnel shortages and lack of training

in certain geographic locations. And the conflicting roles of audiologists who have doctoral education and that took a long time coming, but the expanded scope of practice of audiology that I know others will speak to this afternoon.

And the differentiation between the training and certification of hearing instrument specialists I think is an area that needs to be explored in a different integrated relationship way that's collaborative versus competitive.

So how can we at question two improve our access? Well, we're going to have 71 million over age 65 in 2029. And although we question the technology savvy of our elder populations -- me among them I guess -- we are still going to be seeing more proactive rights-based involvement in hearing healthcare decision making, a more technology literate and savvy consumer.

My aunt yesterday told me about her Mac needs a new operating system. She's 92, 90-something. Anyway, and her -- and her Kindle and

her iPhone and I was just amazed.

Anyway, mobile phone penetration. Evolution of telehealth, telerehab, and software systems are really going to improve the opportunities that we have for specialist access to reach those who experience disparities who need diagnostics and rehab, health and device monitoring supervision, and communities of practice creation.

We already have targets for hearing assessment for the over 60 populations and those over 70 and yet they're highly conservative and they're not implemented.

The World Bank and WHO World Report on Disability talks about the 80 percent of the 1 billion people with disability living in low and middle resource countries. And Stephen Hawking did the preamble who says we have a moral duty to remove the barriers to participation.

And the numbers of population with disabilities is growing for all the reasons we know and I won't go over now.

But the global drivers are human rights, the poverty reduction, sustainable development goals of the UN that just implemented their -- initiated their 15-year plan, the capacity building needs for both professional and community-based frontline health and rehab workers who understand disability and can help alleviate the side effects.

Healthcare system strengthening and metrics need to improve. And we need to develop systems worldwide that are sustainable and scalable versus the kinds of charity missions we've been doing overseas and in some of the poorer areas of our countries.

So the priority is to get the $2 trillion that are lost to our global economy from persons with disabilities not participating in society. We estimate 400 billion in the cost of disability in the U.S. alone with 22 percent of adults having disability.

The main healthcare goal for the next 15 years from the UN is to ensure healthy lives and

promote well-being for all at all ages. And how we handle these regs I think will be critical.

WHO has developed a global disability action plan from 2014 to 2021 that says we need to strengthen and extend rehabilitation, habilitation assistive technology, assistance and support services, and community-based rehab. And that includes the people with disabilities receive the assistive technologies that they need.

I'll pass this by, but I'm serving on a task for UNICEF on the Global Partnership on Children with Disabilities that also has a task force related to assistive technology.

So the UN Treaty on the rights of people with disabilities speaks to 162 countries developing national disability plans. These disability plans are looking for strategies for prosthetic device manufacturer cost and distribution.

I look to Michael Porter at the Harvard Business School for his writings on how we need to reform our healthcare systems. And he talks about

integrated practice units, measuring outcomes and costs for every patient, moving to bundle payments so that we are covering the cycle of care. And that this will bring down cost. We need to consolidate service, expand to satellite locations, and have information technology systems.

I have a lot of documentation, but I just wanted to show this community-based rehabilitation matrix. This was developed along with guidelines by WHO and it shows the whole rehab picture for hearing healthcare.

The part we're discussing today is the bottom of the health silo. And I would like to urge that we think about in looking at the regulation's revisions that we think about the mental health, psychosocial consequences, empowerment, education, and inclusion of people to participate in our workforce who need the right care and quality care.

So I'd like to urge that the regulations when revised certainly have audiologists at the

center of the picture of valued chain healthcare. Thank you very much.

DR. NANDKUMAR: Thank you, Ms. Cherow.

The next speaker is Heinz Ruch of Amplifon.

Page 266

MR. RUCH: Good afternoon. I will probably not be able to speak as quickly as Alicia, but I'll keep a good pace, too.

So thank you for the invitation to speak today. My name is Heinz Ruch. I'm the executive vice president Americas for the Amplifon group. And I've been in the hearing industry for the last 18 years.

Amplifon is the only global company in the retail sector of providing hearing services and solutions. We operate in 22 countries around the world. In the U.S. we operate Miracle Ear, Elite Hearing Network, and Amplifon Hearing Health Care.

I will outline our position on existing regulations as well as proposed changes by PCAST over the next couple of slides.

Today's framework. We believe that accessibility cannot be looked at individually without taking into consideration public safety and patient benefits.

In 1977 FDA adopted new regulations due to public safety, abuse, and effectiveness concerns. Various states added laws to ensure that the selling and dispensing of hearing aids is delivered by a trained and licensed individual in order to maximize patient benefits.

The FDA supported such state laws in the 1980 final rule on preemption stating FDA also believes that stringent state and local licensing laws will ensure that hearing aid dealers are competent to test hearing and to select and fit hearing aids.

Let's have a look at the results such a balanced approach has provided over the last years -- last 40 years basically.

Adoption rates have reached 30.2 percent in the U.S. Patient satisfaction with hearing care professionals is extremely high at 95 percent

over the last five years. Hearing aids have reached patient satisfaction rating of 85 percent over the last four years. Superior to consumer electronic products like smartphones with satisfaction rates at 78 percent according to the American customer satisfaction index of 2015.

Of course we understand that an adoption rate of 30 percent may lead to the interpretation that the market is widely underserved and accessibility is limited due to cost.

Statistics from several European countries where a medical prescription from an ENT's required support the evidence that only 50 percent of those who self-report hearing loss will be prescribed. This suggests that the practical adoption rates in the U.S. are above 60 percent.

Additionally, in the U.K., which provides full reimbursement, 16 percent of those with the prescription decide not to accept and embrace hearing aids. This explains why European markets which provide full hearing health benefits see adoption rates in the 40 percent range.

Prices have therefore limited impact on accessibility. As an empirical U.S. study by Ramachandran with the Henry Ford Health System has also concluded by stating that simply reducing the device cost of hearing aids will not lead to greater acquisition by individuals with mild to moderate hearing loss.

A 2015 consumer market study performed together with McKinsey further supports this evidence by ranking price as the 9th out of nine key buying factors for consumers.

Prices and accessibility today. In regard to price labels we need to compare apples to apples. The prices of PSAPs do not incorporate many technological features used to treat hearing loss effectively as you can see on the slide nor any services from a hearing care professional.

Entry-level hearing aids are close to the cost of premium PSAPs; however, these hearing aids come with technological features and the full spectrum of professional services which ensure that effective treatment is secured.

The primary goal of any hearing device must be to improve speech understanding in noisy situations where a hearing impaired person with mild to moderate hearing loss struggles the most. This requires certain features such as noise reduction, feed can- -- feedback cancellation, directionality and wireless synchronization.

Due to the lack of these combined features, the majority of PSAPs do not meet these minimum requirements for intended use or for effective treatment and will negatively impact customer satisfaction. And those PSAPs should not be labeled or marketed as hearing aids.

With regard to access we see a very competitive landscape market with the full array of points of distributions from big box retailers, online approaches, to many other points of sales.

From a public safety standpoint as already outlined from our European colleague we measured the number of PSAPs in the U.S., as well, and we found the majority to be harmful. Sound pressure levels above 120 dB damage the hearing

after exposure for just seconds for any normal hearing person as well as for hearing impaired people with mild to moderate hearing loss. The majority of these products exceed these levels and therefore they should be prohibited.

Additionally, the majority of PSAPs have frequency responses that do not provide adequate amplification to the mid to high frequencies which are critical for the understanding of speech, particularly for mild to moderate hearing loss.

These products amplify primarily low frequencies which give a sense of loudness, but have very little capacity to improve speech understanding and, therefore, would be detrimental to customer satisfaction.

Another concern. While it might be standard practice for consumers to waive the medical evaluation, state regulations ensure that the trained professional look for medical red flag factors such as wax or foreign objects in the ear to more serious and potentially fatal medical causes like acoustic neuroma.

Trained professional within our national network refer about 6 percent of perspective patients to the medical community for further evaluation. This is in line with FDA expectations that hearing aid dispensers will be conscientious in impressing the importance of a medical examination up on prospective users exhibiting any of these symptoms.

Considering the total hearing impaired population in the U.S., this translates to about 2 million with medical issues which require immediate attention.

Given these numbers, it is unsafe for hearing impaired individuals to self-diagnose and self-treat. On the contrary, the lay person cannot differentiate, diagnose, evaluate, and properly treat the hearing impairment as FDA has stated.

Patient benefits. Treatment of hearing loss with hearing aids involves the process of adaptation which requires multiple visits with a professional. Regardless of the age or severity

of hearing loss, we see all our patients in the first 90 days on average three times to fine tune the fittings as the individual's auditory system and the brain begins to reprocess sound in a more normal manner.

Over the lifetime of a hearing aid, which is six years, we see our patients on average 15 times. These visits and the bundling of services help maximize the effectiveness of treatment, patient benefits, and their satisfaction.

Trust, quality of hearing aids, and professionalism of dispensers ranked first, second, and third out of nine in the 2015 McKinsey study on key buying factors.

When comparing the treatment of hyper optic or farsightedness with reading glasses to the complex adaptation process even in the case of a mild to moderate hearing loss, PCAST makes an unreasonable comparison.

Again, a quick look across the boarders that was already mentioned this morning. The

Japanese market operates similar to what PCAST recommends. PSAPs and hearing aids are not subject to comprehensive and balanced regulation and these products are readily available in all distribution channels at all price levels.

Japan underperforms significantly with regard to adoption and patient satisfaction rates in comparison to the United States.

To the questions of FDA, number one. The strongest barrier to hearing aid access are predominately still denial of need, social stigma associated with hearing loss, as well as missing insurance coverage.

The U.S. study by Ramachandran and experiences in some European countries where consumers access hearing aids for free do not support the assumption that price is the only and main barrier for access.

Number two, in our opinion FDA regulations for products and to dispensing do not create a barrier to hearing aid access, but are basic public safety regulations like the

requirement to obtain a driving license.

In regard to PSAPs, we will propose to have stricter regulations in place for maximum output levels to protect the hearing of a normal hearing individual. We support the FDA practice not to preempt state licensing laws.

Number three, when consumers decide to take action, they and in particular the baby boomers gather a lot of information predominantly through Internet research. Despite having a multitude of options, consumers still prefer to visit the physician or a hearing care professional to seek further advice and guidance to achieve an optimal outcome based on their hearing loss, lifestyle, and financial means.

Number four, we propose the following recommendations to increase the accessibility to hearing aids. Direct CDC and other appropriate Federal agencies to classify hearing loss as a chronical medical condition in order to give Medicare and other third-party payers the latitude to approve reimbursement for professional hearing

healthcare services and periodic hearing exams for older adults.

Number two, endorse the Hearing Aid Assistance Tax Credit Act; and number three, promote a national campaign which creates awareness of hearing loss and of the correlation between untreated hearing loss and cognitive decline to decrease the social stigma.

I conclude, hearing loss is a major health problem. It is growing in importance with our aging population. In order to maximize patient benefit and to protect public safety, we support the product quality standards as defined by the FDA as well as proper treatment of hearing loss by a hearing care professional.

We therefore invite any manufacturer of products intended to treat hearing loss to adhere to the existing FDA standards. Thank you.

DR. NANDKUMAR: Thank you, Mr. Ruch.

DR. BROCKMAN: Good afternoon. Oh, it's working. Good. Thank you for your patience earlier with our technical difficulties-- mentioned earlier my

name is Randy Brockman. I'm the chief medical officer and the acting clinical deputy director in the Office of Device Evaluation.

I am not -- can you hear? better?

Okay. Full disclosure, I am not a hearing expert. I'm neither an audiologist nor an ENT. I'm just a simple cardiologist. But it's a pleasure to be here to moderate the afternoon.

One of the things I would like to do for the Q and A sessions, you know, we have 12 panelists. Four get to speak in each session about the questions. I would like to offer each of the panelists who didn't get a chance to speak about these questions a chance to comment. I'd also like to open up the panelists to ask each other questions about their presentations.

So but I do want to reserve a little bit of time in each session for questions from the audience so if the audience has questions I will try to get to you before we run out of time. We've got about 20 minutes Q and A in each session.

So to start things off, you know, we heard a lot about the barriers to hearing aid access and how (audio cuts out) improve hearing aid access. Some differences of opinion.

So for the folks who haven't had a chance to comment yet would anyone like to add to what was said or comment on any of the other presentations?

DR. FABRY: I think the issue -- this is Dave Fabry. The issue of primary care physicians and 75 percent of individuals going in for primary care eval literally almost have to beg to get their hearing screened is an important point.

And I think it really suggests just a general lack of awareness or a lack of urgency for action that serves as a big barrier. People are coming in often with cognitive dissidence over the fact that they don't like that they have a hearing loss and they may not want to wear amplification, but there's no urgency on the part of the physician to refer in many cases and maybe just of a lack of general awareness of what the benefits

can be.

So I do think that that point is a significant barrier and it's as much related to the physician -- the patient presenting and then the fact that we don't have a sense of urgency in the way that you do if you have a -- you hit 50 and you're going to get a colonoscopy. You hit 40 and you're going to start getting prostate exams. There's no age-related first screening for hearing loss.

DR. BROCKMAN: So just for clarity, you're not saying that it's the need for a clinical evaluation prior to a hearing aid (audio cuts out) speak up.

So just for clarity you're not saying -- you're not suggesting it's the need for the clinical evaluation prior to a hearing aid, that's the barrier. The barrier may be a slightly different point that the healthcare professionals, themselves, may fail to assess or refer for further evaluation.

DR. FABRY: The overlying issue of the

importance of hearing.

DR. BROCKMAN: Thank you. Good point. Other comments?

MR. RUCH: I think along those lines, you know, it would be good like you have to pass an eye exam when you obtain a driving license from a certain age on that it is mandatory that you have to take a hearing test, as well, in order to really promote the hearing screening which is an important part of what we do.

DR. BROCKMAN: Okay. We are -- we do have microphones here, but by all means.

UNKNOWN SPEAKER: Just to clarify, you don't need hearing and you can be deaf to drive and so that's a really poor example and should not be used because I don't want people to think that you need to be able to hear to drive.

In the State of New York if you have two rearview mirrors, you don't -- you don't need to hear -- to be able to hear.

DR. BROCKMAN: Thank you for folks in the audience, at least the front -- front

microphone is working. So if you have questions, please come on up. Go ahead.

DR. CRUM: Thank you for the comment from the audience. I think it's a very key one. The sensory modality most relevant to driving is vision. And it's completely appropriate that we test vision when you go to the DMV. It does not make sense to add on any other health-related parameter that we may choose to assess.

That being said, increasing the -- there's a fundamental problem in the isolation of hearing -- how hearing testing has been protected and almost removed from the consumer or from the user.

It -- you know, there -- this will show up in my talk a bit. But there are so many -- we are health empowered consumers at this point in time. That's happened. That transition has happened. And we want to mon- -- we are monitoring our health in so many different ways, yet hearing health remains almost taboo to a 20 year old, to a 30 year old, to a 50 year old.

I am -- you know, I am not what would be an -- of an age that you would consider me to have presbycusis hearing loss. Yet at the same time I know I can benefit from technologies and from monitoring my hearing.

So there's just a fundamental way that we have to transition the perspective of monitoring our hearing and making is something that is self- empowered and, you know, that doesn't -- that shouldn't be mutually exclusive from the importance of hearing health practitioners and all of those trained in the practice, but it is a critical element that needs to change.

DR. DISARNO: Neil DiSarno. I think just to follow up on the primary care example. We've also heard patients who see their primary care physician who say hearing loss is just a function of aging. You can expect this. I'm having the same problem with my wife instead of saying you do need treatment. There's treatment available for you. I'm going to send you to a

professional.

And I think the fact that even sometimes the medical community doesn't see the importance of this change in health condition, a true change that has so many other implications, I think it's possibly maybe some of our failure not getting that message out, possibly the failure of training not getting that importance out.

But I think if that -- if that level of -- the fact that people are seeing their primary care physician and not getting proper referrals I think contributes to possibly people not getting care until much later.

DR. BROCKMAN: Thank you. You know, it would be interesting to have a primary care provider on the panel to get their perspective on that.

DR. WALLHAGEN: Actually I am sort of.

DR. BROCKMAN: Okay.

DR. WALLHAGEN: But -- but I do think one of the other forces in primary care it -- you -- one, they don't get the education; two, it's a

real time pressure issue for primary care right now. And I know this from doing some work trying to get hearing screening implemented into primary care.

They're already having a lot of what I might call unfunded mandates for screening. And so that they're having to screen for pain, they have to screen for depression, they have to screen for all these other kinds of things. And the primary care practitioner him or herself whether it's a NP or a primary care practitioner physician, they have about ten minutes.

And so they invariably focus on an issue that they know about or they think is a problem. And hearing loss -- and unfortunately sometimes they discount it. So there's a lot of education that needs to occur out there and probably do need mandated screening. But it has to be integrated at certain times so that they know when that's due. And appropriate standardized screening.

DR. BROCKMAN: A lot of competing issues when you see your primary care provider. Yes?

MS. CHEROW: So as usual I didn't get to have my slides. But I wanted to agree with Dave Fabry and I obviously missed the section of my barrier slide where, you know, I talked about hearing loss is invisible, it's painless, it's slowly progressive, the stigma that we've discussed already.

But this lack of the sense of urgency from all actors, during my tenure at ASHA, we had a $2 million campaign to raise awareness among the public. I know that Better Hearing Institute did a major campaign to educate primary care physicians.

You know, among all of our associations there's been tremendous amount of public relations work and yet because it's an invisible disability and because it's related to speech, language, cognition, and now we have even better data on mental health concerns, I think, you know, it's beginning to gain some awareness. But it's been a tremendously challenging piece of the work.

There aren't that many audiologists in

this country and that in itself is another issue. And we're never going to train enough audiologists worldwide to take this on.

And that's why I started but wasn't able to finish to talk about an integrated system of care that Cleveland Clinic has used as one case study. Of course, it's a very different kind of case study. But how do we integrate into practice units and how do we use telehealth and mobile health.

And I was impressed with our European colleague who stood up and showed us, you know, what they've developed on their cell phone. I mean, we need new technologies.

I just have a really big problem with this intended use distinction. I think it's fallacious. Distinction that we're talking about hunting and recreational use. It's an aid to hearing.

And because hearing loss is invisible and because it really needs an evaluation to determine even the mild to moderate category that

someone else raised this morning. The audiogram does not talk about each individual's ability to process an auditory stimulus.

And so I think this -- even the title of mild to moderate adult hearing loss -- the children I've worked with for many years are now middle aged. And 40 percent of them had comorbidities and they are now adults and they have other issues, as well, and as do all of us.

The surgeon general wrote a report on disability. I can never remember his name, Richard Carbona maybe? And he said we will all have disability. But you wouldn't put a limb, prosthetic limb without some physical therapy and yet we're thinking about over the counter as though -- and self-fitting.

While it seems empowering and we don't expect that many acoustic neuromas, we still are creating a barrier to quality care that we would want, the optimal care that we would want our regulations to reflect for people at risk or with losses.

And we all know that people wait until the loss is moderate to severe and I can cite several people in my family who I've taken for audiologic exams in New York City and they said, "I just have a little hearing loss."

My brother-in-law, he's a psychotherapist. When we saw his audiogram I almost fell off my chair that he had a precipitous severe bilateral hearing loss starting at about 1,500.

So I think this category is an erroneous category and I'm sorry I didn't get to the rest of my slides, but I felt I wanted to make those comments.

DR. BROCKMAN: Thank you. Do we have a question in the back?

UNKNOWN SPEAKER: Probably more of a comment. You can all hear me, right? For the non- audiologist, non-ENTs in the crowd this won't seem too strange to you, but I do want to mention many audiologists and hearing aid dispensers, hearing instrument specialists are working in non-

traditional settings now. We have big stores, we have health plans, we have all sorts of other players entering the market.

One of the things that I've always relied on was if I had a patient in front of me or one of the people I supervised had a patient in front of them and they were trying to make the case for a medical referral because of conditions and things they saw in the test results or whatever the case may be, that was easy. We always could use -- we could just say, well, the FDA requires it because there's resistance many times to getting that medical evaluation. People want to skip that step.

The people counting the money, they don't want that step getting in the way. They want that money grabbed that day or whatever -- however you want to word that. I shouldn't say -- that's my opinion there so backtrack. They want that money collected that day, how's that?

So if you are a conscientious provider and you know that there's a need for that you are

put in a real position of conflict. That will happen more and more the more we get away from people in the health professions understanding.

I've never had to explain that before and more recently I did and I had to make the argument. And sometimes you would have people showing up with the medical clearance in hand before they'd even seen us. That make sense to any of the audiologists?

Here's my medical clearance. I didn't test you yet, I didn't see you yet, I didn't take a case history, but somebody on the phone told you to bring this form in? Seriously?

That's what will happen. I don't -- I don't envy the FDA and the decisions that are going to need to be made here, but I do want to say before we rush to get rid of that medical evaluation and/or the waiver, we need to think through all the ways it could be abused.

DR. BROCKMAN: Thank you. Any response to that?

So I just -- we're almost out of time

for this sessions. I just wanted to follow up on one thing. I think it was Mr. Ruch I think you mentioned a report that said that cost was actually one of the least important things as in terms of the barrier on a slide where you listed several of the issues that were more important.

I jotted them down. Right. I think trust and performance were two of them; is that correct?

MR. RUCH: Yeah.

DR. BROCKMAN: Was that -- was that trust and performance in the device or in the provider or something else?

MR. RUCH: Trust was in relation to brand or the provider very clearly so. And the second was quality of the product, itself. So that relates to this. And the third one you mentioned?

DR. BROCKMAN: I didn't actually. I couldn't remember the third one.

MR. RUCH: And the third one was the professionalism of the dispensers which they --

which they qualify as an important key buying factor according to over 2,000 respondents we had in 2015.

So that's the ranking which is another -- it's not a proof, you know, but it's an indication that there are other factors which are equally if not more important than just price, you know.

And I think, you know, there is this discussion which obviously there are different opinions around about bundling of prices or unbundling of prices.

Bundling, according to some literature which we have heard here today too, can lead to reduced pricing if it's taken from the very beginning to the very end which is something -- a concept which is adapted by Medicare now, too, that they have value-based bundling, you know, whereas others differ from that opinion say no, unbundling leads to less cost. We believe it leads to higher patient benefits because, you know, it leads to compliance of care which is

truly important in the landscape role we're all operating in.

DR. BROCKMAN: Okay. Go ahead, who wants to?

DR. WINDMILL: Well, I'd like to -- this is Ian Windmill. I -- the cost is an interesting factor when we talk about cost and especially in the context of a chronic health condition.

And when you look at other chronic conditions such as COPD without exacerbation or low back pain and those costs, those run into the thousands of dollars annually per person.

Comparatively, the cost for two devices even at the rates that PCAST reported of $5,000 over a five to seven-year period is relatively low. Low back pain has incremental costs of about $4,500 a year. So that's almost in one year what a hearing - - hearing care, the full gambit of hearing care costs.

So the difference is is this is a one-time out-of-pocket cost as opposed to things that tend to be covered or you're paying out over time.

And so the cost is a little -- it's kind of a -- it doesn't reflect value either. Value and cost are two different factors.

And so when we talk about cost we kind of have to have an expanded conversation about not just that it's $2,500, but what the long-term costs are, what the incremental costs are, what the -- what the reduced cost for other things like maintaining employment and things like that are, as well.

So I think we have to put cost in a different context than simply what the devices -- the median or typical cost is for the device.

DR. BROCKMAN: Thank you. Any other reactions? Yes, Scott?

DR. BEALL: One other point around cost is I think we have to be very careful when we ask patients what would it take for you to get hearing healthcare or why don't you have hearing aids.

Survey results like that I think you're going to get cost as a barrier, but I don't know how valid that is. It's valid that that's their

opinion, but if you take that same patient and reduce the cost to nothing, would they then do what they say they would do and get hearing aids?

So I think we may be putting too much emphasis on this -- on the cost issue because we don't know for sure. I mean, we can look at adoption rates of people in insurance plans when they can get their hearing healthcare for free. You don't have 100 percent adoption rate in those cases.

So I think we need to look really closely at that adoption rates in other countries that have nationalized medicine. I think that'll give us a truer picture of what role cost plays in the fitting and the adoption.

DR. BROCKMAN: I think we're out of time on the first.

DR. NANDKUMAR: Yeah. We got another session.

UNKNOWN SPEAKER: Can I add something to the cost thing? Sorry. But you said we could stand here.

Actually those statements are very self-serving because the costs were done by McKinsey who I assume was under an in by your company where as when Goldman Sachs -- right. So that's very self- serving. You have to look at who was paying the bill for the person who did the survey when you look at surveys is always a critical -- I have a background in marketing before my law degree.

And so one of the things when you look at Goldman Sachs' report and it was given to me by Lloyd Blankfein to be able to use for lobbying for this issue. And one of the things when you look at hearing aid coverage in Europe that Goldman Sachs did which had no skin in the game, they were trying to just look at the entire market to see about financing and hearing aid companies, then you saw when hearing aids were covered in Europe the usage went up.

Yes. I do think stigma is a huge part of it, but it is a huge barrier to people not being able to afford. Think about it. Even for FDA workers try to pay $8,000 for hearing aids,

good luck with that for most FDA not at the top level.

And hearing aids are not covered. It was taken out on the senate side and I was told by the senator because no -- from essential health benefits because no one lobbied for it. I was the only person on the Hill lobbying for hearing aid coverage with Aiken Gum. That's insane.

And that's because of the huge grip the six companies have on the entire market.

DR. BROCKMAN: Thank you for your comments. Okay.

DR. NANDKUMAR: Okay.

DR. BROCKMAN: Onto session 2.

DR. NANDKUMAR: Thank you. Thank you, Randy, and thank you the four speakers on this session.

We're going to move onto session number 2. Yes. And that's PCAST proposed stratification of hearing aids.

Up to present is Ian Windmill from the American Academy of Audiology.

DR. WINDMILL: Good afternoon, everyone. My name is Ian Windmill. I am the clinical director of audiology at Cincinnati Children's Hospital Medical Center as well as president elect of the American Academy of Audiology. And on behalf of our members we appreciate the opportunity to be able to speak with you today.

You asked that we respond to three questions which briefly flashed on the screen. I hope everybody got them. They were part of the genesis of the -- had their genesis in the PCAST report.

I want to provide just a little bit of context before we get to the answers to those questions.

First of all, our membership does include clinicians who do provide hearing care. And thus my presentation is primarily in the context of clinical service delivery.

Hearing care in this case includes both the assessment and diagnosis of hearing loss, determination of the etiology of that loss, the

impact of that loss on communication function, and the development of a comprehensive treatment plan that may or may not include amplification.

Secondly, the PCAST report continuously referred to hearing aids as a consumer electronic device even though the FDA, as we've heard today, has regulated these as medical devices for years.

For our community hearing aids have never been a consumer electronics and, therefore, any parallels to consumer electronics are not part of our conceptual framework nor are they part of our clinical practice.

Thirdly, we also want to note that successful outcomes, as you've heard today, in the treatment of hearing loss with any device, generally requires an understanding of the complex interaction between the auditory system function, a patient's specific listening needs over time, the acoustic signal, itself, as well as the acoustic environment in which that signal exists, the signal processing capabilities of a device, and the cognitive and physical capabilities of the

end user.

Thus, when we identify the advantages, disadvantages, benefits, and performance outcomes, that does not lend itself to simple explanations in ten minutes.

The first question you asked us to respond to was whether patients can self-diagnose, self- treat, and self-monitor a mild to moderate age- related hearing loss.

The concept of self-diagnosis implies the ability of the patient to determine the etiology of the loss, the type of the loss, and the degree of the loss. This is not the same as self- identification of a communication problem or to identify when a functional limitation exists or when participation restrictions exist.

In this regard we would argue that patients can self-identify hearing problems, but that they do not have the tools, knowledge, or data necessary to self-diagnose mild to moderate hearing loss or age-related hearing loss.

There are a growing number of tools out

there, however, such as smartphone apps that are available for patients to assess their hearing without the need for professional evaluation.

In their present form, however, these tools provide general classifications of loss or function, but they cannot provide comprehensive data on degree or configuration of loss, the type of loss, or the etiology of the loss.

As such, we support the concept that any hearing evaluation device or hearing evaluation application that's made available to the consumer to describe their loss be labeled as a screening tool rather than a diagnostic hearing test.

In many circumstances patients are able to differentiate symptoms that are commonly associated with specific disease processes such a otalgia or otorrhea, sudden unilateral hearing losses, severe tinnitus or the like.

And they are then able to make appropriate decisions to seek medical evaluation. However, we do not expect that this is the case under all circumstances.

Using a patient questionnaire, Dr. Dave Zapala in a presentation to the IOM last year, noted that patients were able to identify ear disease cases 90 percent of the time, 10 percent not, and were able to identify benign age-related hearing loss only 70 percent of the time.

Similarly, self-treatment cannot occur in the absence of a diagnosis. The symptom of hearing loss is loss of communicative function or participation and, therefore, individuals may seek to self-manage as opposed to self-treat their communication deficits but they would not be treating their hearing condition.

Currently the vast majority of patients with mild hearing losses must be self-managing because only about 10 percent of those persons actually have a hearing aid.

With regard to the concept of self-monitoring, it is more likely the patients can self- monitor their functional communication status. As opposed to their hearing status, they can monitor their communication status.

But even today we do ask our patients to monitor their hearing for any functional change in communication, to note any acute changes in hearing, or the onset of related symptoms such as tinnitus or dizziness.

The second question asks for comments about the advantages and disadvantages of a distinct category of hearing aids as over the counter.

Hearing aids and PSAPs as we've heard today exist as two distinctly different categories of amplification devices. And as noted earlier, hearing aids are designated as medical devices and are regulated while PSAPs are unregulated consumer electronic devices.

As such, we believe the creation of a second class of hearing aids that are unregulated would create confusion both for the consumer as well as the audiology community.

Therefore, we suggest there remain only two classes of amplification devices -- hearing aids and PSAPs. Any over-the-counter device used

to manage hearing loss should not be labeled as a hearing aid, but rather as a PSAP even if these devices have similar characteristics to hearing aids.

As also noted earlier, there are significant interactions between individuals' listening needs, the acoustic environment in which they live, and the specific signal processing capabilities of amplification devices.

For example, directional microphones one has sounds coming from the front, but will degrade speech coming from the back. While a consumer may be able to select a device that sounds like it may address their most pressing problems, they will not have any ideas of what they're giving up in making that choice. Thus maintaining separate and distinct categories will work to a patient's advantage.

Under the assumption that any over-the-counter device, including PSAPs, are made available to manage hearing loss, the Academy believes that certain acoustic regulations should

be regulated, as you've heard before, including the gain and output having preset maximums. These levels should be clearly distinguishable within the labeling of the devices.

In addition, we support the labeling of PSAPs with the following: One, that an audiologic evaluation is recommended prior to purchasing any device. That an audiologist or physician should be consulted if any red flag warning signs are present. That the best outcomes are achieved when coupled with a comprehensive treatment plan. That the devices are not intended to be used by individuals with more than a mild loss, and, five, they are not intended to be used by anyone under the age of 21 unless professionally recommended.

As there is little to no evidence on the outcomes use of these devices, they Academy currently suggests erring on the side of safety.

Some of the general advantages of permitting OTC devices include that there's an obvious reduction in cost and fees for office

visits, there's potential for greater utilization of hearing aids as they -- as PSAPs could serve as -- or over-the-counter devices could serve as a gateway into the system. And they may provide a low cost option for those that are in -- without the financial resources or geographically unable to access services.

Conversely, the disadvantages include that the rules for the medical evaluation would have to be reconsidered if you have two classes of hearing aids; one with a medical evaluation requirement and one without.

How will the professionals, the audiologists, who dispense both devices determine the correct requirements for each patient?

There's the potential for additional hearing loss due to improper amplification or the potential for other complicating factors such as cerumen impaction or otalgia for improper fit.

Finally, the third question asked about the implication of wide availability of OTC devices that would be for patients other than

those with age-related mild to moderate hearing losses.

We believe that the inability to diagnose forms of hearing loss will result in the use of over-the-counter devices by persons other than those intended. Persons with conductive losses or more severe forms of loss or those with atypical audiometric configurations will also try these devices. But we believe with appropriate labeling and consumer education the risk can be reduced.

Infants and children are a unique population and those identified with hearing loss are generally managed by audiologists from the point of identification forward, including providing amplification devices as part of the treatment process; however, there does remain the potential that parents may choose a low-cost option due to their socioeconomic status, insurance coverage, or access to quality hearing care.

The likelihood of parents choosing an

OTC device to manage hearing loss in the pediatric population is low, but the implications for social education are much more significant than the adult population.

On behalf of the Academy we again appreciate the opportunity to meet with you today and stand ready to assist the FDA in their investigations and deliberations.

In ending, discussion about accessibility and affordability we do believe consumer safety must be part of the conversation. Thank you.

DR. NANDKUMAR: Thank you, Dr. Windmill. Next speaker is Dr. James Denneny from the American Academy of Otolaryngology Head and Neck Surgery.

DR. DENNENY: Thank you very much. I'm Jim Denneny the executive vice president and CEO of the American Academy of Otolaryngology Head and Neck Surgery. And on behalf of our group, thank you for the opportunity to comment.

I'm also a practicing otolaryngologist

that's been seeing hearing patients for over 35 years, but do not receive any income from medical practice currently. I have no conflicts to discuss.

There's significant momentum both in the United States and worldwide to increase utilization of hearing healthcare services, particularly the adoption of technology designed to improve the hearing of those with significant loss.

The AAO-HNS recognizes that to accomplish that there's going to be -- have significant changes in the system. One of the opportunities that I think we have in today's time due to a confluence of technology changes and opportunities is to make those changes.

Most would agree that these are common problems that we look at. Hearing loss adversely affects all facets of life. Diagnostic and therapeutic services as well as technology that is used to help those problems are underutilized in the United States and worldwide.

As you've heard, insurance coverage is spotty and variable. And there's multiple factors that are not limited to costs that contribute to the problem.

But one of the things that we do see is the significance of the stagnation of the utilization of the system. With all the resources it's not getting better so something must be done to move the needle.

Part of the problem the barriers to entries you've heard so far one is the realization that you have a problem; two is the denial of the problem even when you're family members or colleagues inform you of it.

There's also still a remaining stigma of the diagnosis of hearing loss even though that this society is much more recognizing disabilities of all types.

And perceived complexity of the cost and access of the system. As you've seen a very nice slide on how difficult it was, what's going through the patient's mind on what do I do,

there's so many options.

The negative experience either personally they've tried something or one of their family members or colleagues have tried something.

And then the -- as also mentioned, the expectation that just like arthritis as you get older you're going to get a hearing loss and there's nothing that can be done for it. That's been a failure on our part, everyone in this -- at the table of promoting what really is a problem with hearing loss.

So what I'd like to look at is realistic interventions that could be accomplished in the current situation that we have economically in this country and politically.

One of the things that I think's important whatever system you do, and you've heard this, is to do no harm. We need to look at simplifying the entry into the system. And some of the self- screening options you've heard about are valuable.

And then what's out - there the devices

that are available particularly for the lesser hearing losses need to be something that's simple, basic, and familiar similar to what is seen if you just ride an airplane today how many people have various devices on their heads. So I don't think that that's a problem anymore.

We also have to reduce the cost of evaluation and the devices, themselves. Now, again, you've heard multiple reasons why this may or may not be a factor. But I think if we're looking to move the needle we're going to have to change some things.

Technology advances right now will add -- will allow accurate screening. In no way am I saying this is similar or even close to being equal to a di- -- a complete diagnostic audiologic work up, but it does allow the actual diagnosis of some hearing loss.

One of the things we think that will happen with this if people have this on the phone, their computer, or whatever you will find people that are identified as hearing loss that may have

been in the group that did not recognize they had it. These people will then get themselves into the system I think more frequent than they do now.

One of the things that we think is important is a medical exam both to confirm the -- confirm the fact that that is the correct diagnosis. In our mind the fact that we're looking at -- sorry -- at incorrect diagnosis even with these hearing screenings these devices we're talking about today are looking at mild to moderate hearing loss and ones without underlying disease.

So the an- -- the medical examination rule out anatomic or medical problems and then they can outline the treatment options and expectations. The consumer then could choose from a full service option or an over-the-counter option.

The question was raised about ongoing monitoring. These particular devices that are available and will become more prevalent in the future just as they are for other disease

processes will allow an inexpensive serial examination at home where you can monitor not only the hearing, but it could possibly identify failure of the device. This does not monitor the communicative skills, but it does give an easy way to see if your hearing's changing.

Most of the time there's the -- there's an expected progression of loss over time. And as -- if they are able to identify that that hearing loss is worsening, we think that will drive them into the system for a more comprehensive evaluation.

Looking at the entry-level devices we're actually quite concerned about PSAPs. You've seen some of the -- one gentleman had the slide about the gain all the way up to 130 and 40 decibels on some of these PSAPs that were studied in Europe. Very dangerous as far as potential hearing damage.

So if these are allowed and marketed they need to absolutely have manufacturing standards and need maximum gain levels on each of these devices.

Entry-level hearing aids should also maintain production standards not only for clinical response, but again to prevent injury. If they do go over the counter if you approve that, then they need gain control, as well.

So looking at some of the implications of over-the-counter availability. One of the things that as an otolaryngologist -- and I think everyone in the room would say at one point we actually need to do no harm. So if we're going to change this system we need to limit the risk to patients.

As far as patient groups, pediatric patients, most -- most children in this country, over 56 percent, are covered by Medicaid. And the majority of states have hearing benefits for under age 18. They certainly don't for most adults, but for the under the age 18 they do even though it varies state to state.

But we feel these are absolutely inappropriate devices for the pediatric group. They need a full evaluation medically and

audiometrically to ascertain something that's going to be with them for the next 8- -- up to a life expectancy of 80 years.

I wanted to talk about adult patients with conductive hearing loss. I'm sorry, this is -- those patients typically are caused by a number of things, but some of the things are designed to be seen by the red flag surveys.

Anything that would be a treatable cause such a perforation, otorrhea, cholesteatoma, things of that nature would be picked up on a medical exam. Once the external auditory canal issues are corrected and the ear was deemed safe, then an entry-level device for a mild or moderate conductive hearing loss would absolutely benefit many patients. It wouldn't be all, but it would be many.

The severe to profound sensorineural hearing loss certainly would not be something the devices we're talking about would help in any respect. It would not pass the indications for use of those devices very unlikely to provide

improvement.

Those with some above-average residual discrimination would possibly get some benefit from it, but the goal would be if they got some benefit from that they would end up going to the system and going up the ladder and getting the full audiometric evaluation and rehabilitation services. These devices would not be suitable for that group.

So looking at this, our conclusions and recommendations. These are based on the fact that if this country wants to move the needle there's going to have to be some give somewhere because we've had good devices available particularly the last ten years for severe and profound hearing loss and we don't seem to have any real increasing penetration.

I would be a little concerned about taking the European and the Japanese data as far as what will happen in this country. There's a lot of tendency in our population to adapt to new things and new technology.

So what we recommend is a do no harm strategy that expands consumer options based on the following recommendations and use it as a pilot program, possibly a five-year pilot to see what happens.

Consumers could identify a mild to moderate sensorineural hearing loss either by a screening or full audiometric testing. A medical exam by a physician would confirm the diagnosis and outline strategy.

Entry-level hearing aids would be available over the counter or online or through the existing system. And we recommend manufacturing standards for the devices along with red flag warnings to be required and that includes PSAPs. Thank you very much.

DR. NANDKUMAR: Thank you, Dr. Denneny. The next speaker is Neil DiSarno from American Speech and Language Hearing Association.

DR. DISARNO: I'd like to start off by thanking you for the opportunity to speak today. My name is Neil DiSarno and I'm the lead

audiologist at the American Speech-Language-Hearing Association, commonly known as ASHA.

ASHA represents 186,000 members, almost 13,000 of which are audiologists. ASHA represents more than 91 percent of practicing audiologists in the United States.

No financial interest other than the fact that I am employed by the American Speech-Language- Hearing Association.

Okay. And the --

UNKNOWN SPEAKER: I can't go any further, sorry.

DR. DISARNO: I guess I've said it all.

(Brief pause). That's not it, though. Let's see, can you go back?

UNKNOWN SPEAKER: Yeah. Let me just try this one. Can you tell her to advance the slide?

DR. DISARNO: Go back. Sure.

(Brief pause). Thank you. Hearing and balance disorders are complex with medical, psychological, physical, social, educational, and employment implications.

Treatment services require audiologists to have knowledge of existing and emerging technologies as well as interpersonal skills to counsel and guide patients and their family members through the rehabilitative process.

Audiologists provide professional and personalized services to minimize the negative impact of these disorders leading to improved outcomes in quality of life.

ASHA fully supports greater access to and affordability of hearing healthcare along with any other appropriate device or treatment for individuals who are diagnosed with hearing loss.

We've already seen big box retailers enter into the hearing aid distribution market and Walgreens and CVS are conducting pilot programs in order to enter the market, as well. These, along with online retailers, now account for 10 percent of the U.S. market.

Although these new distribution models have resulted in the cost of devices being driven down and accessibility for consumers increased,

the absence of auditory rehabilitation in these models limits successful adaptation to hearing aids.

Let's begin by considering the implications of hearing loss in adults. While most people consider hearing loss to be a condition of aging and confined to the ears, evidence suggests that considering hearing loss as age related is an incorrect conclusion.

Hearing loss is a multifactorial genetically-driven process that gradually leads to cell loss and change in -- changes in physiologic responses within the ear. This stress is caused by damaging factors such as noise, infectious processes, and other systemic factors.

Hearing loss in the adult population is more likely due to the cumulative effect of these genetic and systemic factors over a lifetime rather than aging alone. Because the most common forms of hearing loss in adulthood are persistent, permanent, progressive, and impose functional limitations, hearing loss meets all the definitions

of a chronic health condition.

Alternations occur within the auditory system which include a reduction of the number of and function of brain cells and nerve cells that determine sound perception and also communication function.

Recent evidence also suggests a correlation between hearing loss and depression, dementia, and even mortality; therefore, classifying hearing loss as an age-related phenomena is simplistic and ignores the extensive nature of the problem which often includes physiologic, psychologic, and functional implications.

Individual treatment and counseling is required along with appropriately fitted devices in order to address the multifaceted disabling effects of this chronic health condition.

You've asked us to answer three specific questions that derived from the PCAST report. The PCAST report focused solely on the hearing device. The device is only one part of a rehabilitative

plan for treating hearing impairment.

Just as a knee replacement without accompanying physical therapy strictly limits patient success, a hearing aid without accompanying hearing therapy, otherwise known as auditory rehabilitation, strictly limits alleviating the debilitating effects of hearing loss.

Over-the-counter hearing aids pose the most danger to the public in the case of a parent purchasing them for a child. Our concern is that it will be tempting for some parents to purchase an over-the-counter hearing aid for a child if it's priced at a lower cost because it will not include any medical or audiological services.

Children with hearing loss are at significant risk for severe complications due to untreated ear disease, inadequate amplification leading to severe, permanent, and disabling language impairment or even additional hearing loss because of inappropriately high levels of amplification. Children must have appropriate

medical and audiological care for their hearing loss.

The obvious advantages of making a class of hearing aids available over the counter are access to products and assumed lower device costs. Unfortunately, the disadvantages and associated costs far outweigh the advantages.

ASHA has serious concerns about the recommendation for a new class of over-the-counter hearing aids. Such a recommendation could pose hearing risks to the consumer if the underlying cause is not properly tested and diagnosed by a hearing healthcare professional and if the device is not fitted properly to the consumer.

As recent research shows, untreated or undertreated hearing loss has serious consequences for brain health. Why would we allow people to self-diagnose and self-treat a condition that has such serious implications?

Over-the-counter devices intended to address hearing loss in adults with mild to moderate sensorineural hearing loss should be

registered as medical devices because they are intended to treat a chronic health condition.

Furthermore, regulations must distinguish between hearing aids classified as medical devices and consumer electronics that augment hearing, known as personal sound amplification products.

As noted in the PCAST report, the line between PSAPs and hearing aids has become blurred and at times differentiated only by its advertised purpose.

Furthermore, consumers that purchase these devices should be made aware of the FDA red flag conditions and symptoms and be instructed to seek medical care should these symptoms present.

Self-assessment checklist to determine if you have characteristics of hearing loss can be helpful screening tools. ASHA has one available to consumers. Many people can probably tell if their hearing is dissipating or be told by loved ones as the case may be.

Today's Internet-based hearing screening

methods should not be equated with professional diagnostic testing. The Internet methods are simply not capable of providing an accurate diagnosis due to coupling and receiver issues on the consumer side and the inability to standardize ambient noise at the test site. To say nothing of the impossibility of viewing the ear canal and eardrum, a critical consideration in hearing evaluation and potential hearing aid use.

These over-the-counter hearing tests may give the consumer some estimate of loss of sensitivity with no knowledge about configuration or etiology of the hearing loss nor what it means from functional and environmental perspectives. These Internet tests cannot establish the degree of functional limitation, a critical factor for determining the need for amplification.

The Hearing Loss Association of America's own policy states that every potential hearing aid candidate should receive a comprehensive audiological evaluation conducted by an audiologist with an appropriate state license

to practice audiology.

ASHA also believes that consumers are best and most effectively served by undergoing a comprehensive audiological evaluation prior to purchasing any amplification device. That is whether it is a hearing aid, personal sound amplification product, assistive listening device, or phone application. And regardless of whether device, itself, is obtained over the counter, online, or through a licensed dispenser.

The FDA should distinguish between medical devices and consumer electronics to protect the consumer and maintain requirements for best practices in manufacturing.

We have heard from audiologists that consumers are coming to their offices with Internet and PSAP devices with complaints, concerns, and questions. Without professional consultation and fitting, consumer benefit from PSAPs or over-the- counter hearing aids can be extremely limited.

The FDA should maintain consistency in

its regulations regarding hearing aid manufacturing. The healthcare community must message the importance of audiological evaluation and stress the indicators requiring medical attention and consumers need to be made aware of the need for auditory rehabilitation rather than being under the assumption that the device alone with alleviate the effects of impaired hearing. Thank you.

DR. NANDKUMAR: Okay. Thank you, Dr. DiSarno. The next speaker is Scott Beall from the International Hearing Society.

DR. BEALL: Good afternoon. My name's Scott Beall. I'm a licensed audiologist and hearing aid specialist practicing in Ohio. I've been in the hearing aid profession for 34 years. I'm the founder and owner of Beall, Incorporated, which operates 36 hearing aid centers in the Midwest.

And did we figure this out? Oh, right arrow key, of course. It's a button. I'm an audiologist. I should know this. There we are.

Today I'm talking to you on behalf of the International Hearing Society which is -- represents licensed hearing aid specialists and audiologists worldwide. And it may be a good time to mention that half of the hearing aids fit in the United States are by licensed hearing aid specialists.

Thank you for the opportunity to discuss PCAST recommendations, proposed classification of over-the-counter hearing aids. The International Hearing Society is very concerned about the proposal. While the IHS has several concerns, I'm just going to address a few.

The first is the pos- -- subject of possible exemption from good manufacturing processes. While the IHS believes that good manufacturing processes are an issue between the manufacturers and the FDA, we do have a few concerns.

First is that those of us who fit hearing aids have to be absolutely confident that the products that we fit are safe and effective

for our patients.

Second, we're concerned about the effect that removing regulatory safeguards would have on -- excuse me -- have on manufacturers. The premise of PCAST is that a non-regulated subclass of hearing aids would somehow be simpler or of lesser quality than actual hearing aids, but there's no mechanism to make that so.

Sloping sensorineural hearing loss, the most common form obviously of hearing loss in the elderly, requires more sophisticated technology than required for conductive loss, not less sophisticated technology.

If manufacturers are allowed to produce a class of devices intended for hearing loss which are exempt from GMPs and presumably exempt from state licensing laws, why would manufacturers offer any other kind of hearing aid other than unregulated?

If both licensed and unlicensed providers could fit these devices, then manufacturers would have both distribution

channels open to them and it's likely that in a short time most or all hearing aids would be of this new classification. This would result in a de facto deregulation of the hearing aid business.

Why would a provider go to the expense and regulation to become licensed and stay licensed if he or she could fit the same hearing aid without a license?

The FDA has asked whether there may be an alternative or better approach for stratification. IHS simply does not see an alternative to the existing model that would retain the safety and screening standards that are necessary for a proper diagnosis and treatment.

Stratifying based on gain does not work. The gain required for good hearing aid fitting depends on the degree of loss, but it also depends on the insertion depth of the hearing aid.

As the depth of the hearing aid increases, the physical volume between the hearing aid and the eardrum decreases. A smaller volume requires less gain to meet the amplification

targets. So the gain required to fit a hearing loss varies widely depending on the type and style of hearing aid chosen as well as that instrument's fit. And we routinely fit moderate hearing losses with low-gain hearing aids.

Stratifying for gain or any other hearing aid characteristic would still make it impossible to draw a distinction between a hearing aid meant for someone with presbycusis or someone met with noise- induced hearing loss, otosclerosis, or any other medical condition.

While appear to an average between 26 dB and 60 dB, a gradual loss or being over 60-years-of age could be an indicator of age-related hearing loss. The possible conditions reach far beyond presbycusis.

A general -- a study published by the Journal of the American Medical Association indicated that while most hearing loss in the elderly is sensorineural and due to presbycusis, up to 30 percent of these patients may have cerumen impaction or chronic otitis media that

should be treated by a physician.

Neither a lay person nor an online hearing test would be able to detect or diagnose any of these conditions. And people are notoriously bad at identifying their own hearing loss.

In 2009 the Better Hearing Institute conducted a study, a study using mailed surveys, surveys in the mail, asking if someone in the household had a hearing loss. That study indicated that there were 34 million Americans with hearing loss.

A 2011 study by Dr. Frank Lin reviewed the incidence of hearing loss of those who actually had their hearing tested. This more accurate study estimates that 48 million Americans suffer from hearing loss.

This difference of 14 million people is a 41 percent error of self-diagnosed hearing loss versus actual hearing loss. And if we can't expect people to diagnose or identify their own hearing loss, how do we expect them to determine

the etiology of that loss? Well, we can't.

The FDA mandates that hearing aid professionals screen for eight red flag conditions. The screening is critical. Three of these red flags can only be derived by audiometric and otoscopic examination.

In a 2015 poll of hearing aid professionals, IHS found the average practitioner is often referring patients to physicians. Earlier this year I received a thank you letter from a patient that one of my specialists referred to a physician for what turned out to be melanoma hidden in the ear canal. This referral likely saved the patient's life. Although this is rare, I get a letter like this almost every year.

Properly identifying a hearing loss is complex. It requires a series of tests beyond just the standard audiogram and equipment that allows the practitioner to identify the type, degree, shape of the hearing loss, as well as the indication for amplification.

Hearing loss can be treated in a variety

of ways. If a hearing aid is appropriate treatment, there's several important components to the treatment including proper fit, verification of fit, counseling, and aural rehabilitation, none of which the lay person is able to perform.

Excuse me. The IHS supports the current delivery model as prescribed by the FDA. This path provides two opportunities for physician intervention as need. The first is the initial evaluation which may result in a referral to a physician based on red flag conditions.

The second is once a patient is identified as a hearing aid candidate at that point they're advised to see a physician unless they choose to sign a waiver.

Now it's true that most patients once tested and cleared of red flags choose to sign the waiver, but the use of the waiver doesn't tell the whole story. Many patients who screen positive for red flags are referred before given the opportunity to sign the waiver.

While the PCAST has targeted a limited

population, it would be impossible to restrict the sale of these devices for this intended use. Selling these hearing aids in retail outlets like pharmacies and consumer electronic stores would only make things worse.

This would result in individuals with all types of hearing loss purchasing these devices over the counter sometimes unnecessarily and often with the result of delaying necessary medical care.

We can also see parents purchasing these hearing aids for their children which is particularly alarming because of the critical need for audiological intervention and training during these formative years.

It's plausible to expect that many individuals with more severe hearing losses will seek to self-treat with OTC hearing aids which will have little value to them. This may lead them to believe that no hearing aids can help them.

Enabling hearing aid fitting without a

license would circumvent state-based consumer protections that were suggested by the FDA when hearing aid rule was first adopted.

The FDA, itself, stated that labeling regulations and restrictions on hearing aid sales was only a partial solution to problems that existed when hearing aids were unregulated.

They supported the use of state licensing to keep unscrupulous, unfit, and inept practitioners out of the field of hearing aid dispensing and it's worked.

As envisioned by the FDA, all 50 states now regulate the fitting of hearing aids. Most, if not all states, require providers to prove that they're free of infectious and contagious disease and have no criminal record.

The consumer complaint procedures and the state laws weed out bad actors. It's frightening to think of the risk to our senior population without these critical protections.

As recently as 2004, the FDA reinforced its belief in the importance of the role of the

physician and licensed healthcare -- hearing healthcare professional. The FDA took great caution in developing the rule to provide the proper amount of regulation and to keep the cost of regulation as low as possible.

Now we're back revisiting the core functions of the rule when in reality nothing about the devices or the pathology has fundamentally changed. If anything, recent research has uncovered a number of new comorbidities associated with hearing loss to strengthen the need for a licensed hearing care provider.

The HIA study indicates that a number -- the number one reason, as Heinz said, for hearing aid delight, is the hearing care professional. In fact, at least six of the ten top reasons involve the professional fitting the hearing aid.

PCAST would lead you to believe --

DR. NANDKUMAR: You're out of time so.

DR. BEALL: Okay, yeah. Fine. Our recommendations are for the FDA to reject

proposals to create over-the-counter classifications of hearing aids and reject the proposal to eliminate the 2013 guidance on PSAPs, instead adopting the 2013 guidance. Thank you.

DR. NANDKUMAR: Thank you, Dr. Beall.

DR. BROCKMAN: Great. Thank you very much to the speakers.

My take on the first question, at least, was that most of the speakers were skeptical of consumer's abilities to self-evaluate. I would be very interested to hear some of the other --

DR. CRUM: Sorry. Can you hold the mic closer? It's very hard to hear your ediction.

DR. BROCKMAN: Sorry. It sounds loud to me. I said -- pardon? My -- my take on the speakers was that most of them, especially on the first question, were skeptical of consumer's abilities to self-evaluate hearing loss.

And I would very much like to hear from some of the other panelists to see if there are any other opinions. Yes?

DR. FABRY: I think even the question

that says self-monitor mild to moderate age-related hearing loss begs the question really that was raised by several of the presenters of whether mild to moderate hearing loss is a normal part of aging or whether it's a medical condition.

And I think evidence-based research from NIDCD, NIH, and other funding agencies has suggested and shown a strong correlation between Neil mentioned cognitive decline and untreated hearing loss, but I think there's a wealth of literature showing correlations between hearing loss and cardiovascular disease, for example. Diabetes, hypertension, et cetera, smoking all elevates risk for hearing loss.

Many cardiologists will say that the ear in the aging individual with no history of hearing loss is a good overall barometer of cardiovascular health. And so I think the issue that in isolation a mild to moderate degree of hearing loss may, itself, not present significant challenges, but in an integrated health plan may suggest strong evidence supporting and correlating

to other health conditions.

And I think it behooves us to get more research to that effect, but I think there's already a significant amount of evidence in place that shows, number one, that it is an important medical health condition and should remain an important medical health condition even for those with mild to moderate loss.

And what Ian showed about the ability of individuals to not be able to self-diagnose mild to moderate degrees of hearing loss it seems a strong contradiction that we would then label PSAPs as being only for mild to moderate loss when they can't self-diagnose it.

DR. BROCKMAN: So you're in the boat -- wait, you're also concerned. Yeah, okay. Are there -- anybody can speak up, but I'm curious if anybody feels differently.

DR. KILLION: I have a very simplistic thing if everybody wants to know of a simple hearing aid or a simple PSAP would work.

Does your wife express annoyance at how

loud you have the TV set and how loud she has to talk? And if the answer to that is yes, you have another question, is that sufficient for you to understand them? And if the answer to that is yes, all you need is some gain for quiet sounds.

DR. CRUM: So regarding self-diagnosis. I whole heartedly agree that an individual with hearing loss is very poor often until it's quite substantial in identifying that loss.

However, we -- there are many metrics that are widely deployed in science -- you know, in -- throughout science, throughout the audiological community that development of standardized methods that could be deployed to the consumer, to the user that were -- I mean, that were well tracked is a very, very real thing that can be done.

I mean, psychometric testing, physiological testing, but things that can be done on an -- I mean, having -- the fact that there are so many different approaches and it's actually becoming a commo- -- you know, something that's,

you know, a proprietary distinction among different companies for how you test hearing and who has the best method to identify these things to me is a little bit backwards.

We should be identifying how we come up with metrics that are common. We had the technological capabilities to mitigate or to identify the noise floor of where someone is testing and to mitigate that with regard to the metrics that we're capturing. All of these things can be tracked with the state of today's technology.

What we need to do is empower our consumer and empower the user to treat hearing health as something that they monitor in the same way they monitor their temperature.

DR. BROCKMAN: So if appropriate methodologies and technologies were available, you would --

DR. CRUM: Yes.

DR. BROCKMAN: -- be in favor of it?

DR. CRUM: But we -- standardization is

very important I believe.

DR. BROCKMAN: Fair enough. Yes, Evelyn?

DR. CHEROW: We've had a lot of research over the years on functional assessment scales in audiology and oral rehabilitation.

You know, when we were developing the hearing chapters for Healthy People 2000- -- 2020, you know, we met with the people from the National Center on Health Statistics who have to come up with the data.

And the National Health interview survey and we've been happy with it, but we've had to live with it because we didn't have direct assessment of the entire population or the sampling or the sampled population where we could actually do an audiologic evaluation.

But I -- I have a question for Dr. -- I'm sorry -- Denneny- -- please, related to you had mentioned that screening tools that are being developed online and mobile apps and so on might be used by the ENT for moving forward for an

evaluation.

And I always thought that from a professional liability and risk management perspective that the gold standard would be an audiologic evaluation before a physician would make a diagnosis of type, degree, and medical treatment.

So I'm curious if you're saying that you would proceed without an aud- -- a full audiologic evaluation to diagnosis with a self-evaluation?

DR. DENNENY: Sorry. No. The answer was unclearly presented, then. The screening would bring them to the office where, to me, a full medical evaluation of a hearing loss includes a complete audiogram and audiometric evaluation.

And that's my -- that's a definition I should have explained. But we -- if they came to the office with that audiogram and said, you know, this was what I got, I would look in the ear, we'd do a full audiogram, and then compare to what they got.

I would like to make one other comment.

I didn't comment the last time about the primary care before we jump on the back of the primary care.

If people come to a primary care with a stated goal “I need a medical clearance for a hearing aid”, that's different when they come in and say “I've got pain in my knee and by the way I'm not hearing as much.”

If they came in with that goal they would be investigated and the ears would be looked at. So I don't want to throw them under the bus unnecessarily because when you come in with seven complaints in a day, as someone stated, it's different than if you come in specifically I need a medical clearance.

And so just to make that point I think that they're very competent people and they do try to do the best for their patients even though you can't get every complaint on every visit.

DR. BROCKMAN: Thank you. Good point. Other comments? Alicia?

DR SPOOR: So I want to play devil's

advocate for a minute kind of going back to your first question and I don't have an answer for it.

But when you're talking about can consumers self-diagnose, treat, and monitor hearing loss I'm curious -- and I don't expect an answer -- if the FDA went through this entire proceeding if I changed the question to can consumers self-diagnose, treat, and monitor foot pain, headaches, tooth pain, lower back pain, a wart on my finger just to maybe think about that a little bit more, too.

DR. BROCKMAN: Fair enough. I think I get your point. Oh, thank you. Yes, sir.

UNKNOWN SPEAKER: I have a question for the panel. The issue of whether or not consumers can self-diagnose I think is a little bit of a red herring because obviously you're asking consumers whether or not they have medical knowledge.

The question I have is an operational one which is can a consumer, given the proper user interface of a hearing device, do you believe that a consumer could adjust the performance of the

hearing device in terms of its amplification, its equalization, perhaps its compression such that they would be able to gain efficacy from it or do you think that something like that is beyond the capability of consumers?

DR. BROCKMAN: Go ahead.

DR. CRUM: Thank you. I'd say absolutely, but I'm speaking from a different industry. And I also want to quantify what I said before where I said that I think the consumer -- it's very difficult for them to identify hearing loss. What I mean is perceptually to be on -- to be introduced to that point.

But once you're working with a device to know what is beneficial to you is something you're very sensitive to. And in -- that paired with standardized eval- -- self-monitored evaluations that are somehow tracked would be very powerful.

DR. KILLION: Years ago there was -- I think it was at ReSound they had a do-it-yourself. More recently Diane Van Tasell and Andy Sabin came up with a very nice cell phone

that allowed you to adjust the gain and the frequency and found out in careful study that after they had used that for a while and they'd used an audiologist they preferred their own adjustment.

UNKNOWN SPEAKER: They confirmed their own assessment? Sorry. My --

DR. KILLION: They preferred, sir.

DR. BROCKMAN: End of the table.

MR STRUCK: Yeah. To address your initial question, what you're talking about really is combination of user interface and training for someone to actually operate something.

And the answer is probably the same as it is for most other devices beyond a certain simplicity. Once it becomes a certain complexity or depth of user interface you end up with a distribution.

You have people that -- a small amount that will pick it up immediately. They're very intuitive users. You have a fat part of the distribution of the population who with a little

bit of training will probably be able to function it. And then you have another tail end of that population that no matter how much training you give them they are not going to get it.

In the old days when we did customer service or technical support the first question was always is your VCR flashing 12? If it is, we can't help you.

DR. BROCKMAN: Dave, go ahead.

DR. FABRY: And I'll speak just from the representative of current manufacturer of technology, as well. And we believe that it is certainly within the capability of people to fine tune and optimize the device beyond the initial professionally set device on the basis of their audiogram.

And so we have products on the market now where they can either use a smartphone or in the clinic a subjective space where they can optimize beyond what the initial settings were made for the audiologist or hearing instrument specialist to set on the basis of their audiogram.

But it's certainly not beyond the capability of the patient to do that in Maine.

UNKNOWN SPEAKER: I have -- can I make small comment?

DR. BROCKMAN: Just, Poppy, did you have a response to the prior question? No. Okay. Go ahead.

UNKNOWN SPEAKER: We are in a -- in a world where you have self-driving cars and we don't believe that you can do self-fitting or self- screening. I'm astonished.

I have grandchildren of four -- grandchild of four and when we were doing the experiments in the beginning with our self-screening test without any explanation she done the test. And she's doing this test fairly regularly.

So I think you would not underestimate the capabilities of technology and deep learning and other mechanisms which we have available currently in our technology and very powerful mobile phones connect the devices so it's really

possible.

So it's not about the possibility, it's about the technology whether we can implement part of testing and whether there's enough to do a real assessment and a real diagnosis. That's really different.

DR. BROCKMAN: Poppy?

DR. CRUM: So much agreed. And to that point and to Richard's as well, I mean, these are constrained method of adjustment psychometric tests that people are essentially carrying out on themselves which has a hugely long history of being very successful and very sensitive in different dimensions.

But the onus is on the developers to recognize that there are great interactions on different dimensions and to create -- you know, create blanket -- blanketed user interfaces and interactions between those features and parameters that are intelligent and don't have the user get stuck in a local minima which is very, very attractable today so.

UNKNOWN SPEAKER: If you talk about for instance about awareness about hearing loss, if you make it tangible by having someone doing a screening every week if you have a prob- -- if you have a problem or a concern, you can see what's happening.

You go to a concert, you do the test again. And that's really possible and feasible. So and if you later go to an audiologist or you let your audiologist take a look at your audiogram which is dynamically on the web you can have a much better history about, hey, what's happening.

So I think it's only very beneficial the technologies for -- for helping your patient or your client or your customer.

DR. BROCKMAN: Okay. Thank you. You have a question up front and then I'll get to the back.

MS. GERHARDT-JEWELL: I have to agree at a clinical level that everything that everybody has said about having a screen and being able to find where you can hear and what you like about

different situations is absolutely -- there is a distribution.

We have a patients who take to it the first day and we have patients who will never really be able to do it. That's a matter of function. And one of the things that we look at when people come in is not just the hearing loss, but their functional capabilities and their cognitive capabilities.

And I think that that's the part that we need to remember would be missing with over-the-counter sales.

The other thing that I'd like to say is the Dr. Denneny talked about a five-year study. And I would caution on that because one of the things that we found in Colorado is that it took us eight years after licensure came to get rid of all of the problems that we had.

That's one state that only didn't have licensure for ten years. It took eight years to get to an even keel. If we were to do that on a national level I think we would be inviting a lot

of trouble.

So in that sense I don't think it's a good idea to have deregulated hearing aids.

DR. BROCKMAN: Thank you. Next question?

UNKNOWN SPEAKER: I want to bring up a couple of concerns. One is I've personally spoken with over 100 people who had hearing testing that was not accurate and that I had to inform them they needed to go elsewhere to have it redone. And I saw those retest results.

People cannot tell if they've had an accurate hearing test. Sorry. But if you are -- I don't -- I don't even think it matters intellectual ability, profession. I know we have a lot of engineers out here. You guys are really smart. But it is very difficult for people to tell whether they've had an accurate hearing test.

You can have methodology that is quite well studied, but then that methodology might be put into products that aren't well manufactured or whatever the case may be. So there -- we clearly

-- I think one thing we're finding out from this whole session today we need more studies, we need more information.

Perhaps it needs to be funded by two or three of the biggest stakeholders here. It's not going to be me. I don't have a job right now so don't -- don't ask me. But we need some -- we need some funding of some studies.

And one of the studies, and it's on my Linked-In page -- I'm not a Ph.D., I'm not a research, I'm a clinical person. But I'm a connoisseur of research.

And I put -- proposed a study that we actually go out, ask the man on the street or woman what's your hearing loss like, what do you think you have trouble hearing? Have you ever had a hearing test?

If they've had a hearing test they're eliminated. You know, if they're wearing hearing aids they're eliminated.

You can do some assessments and then do a traditional test, find out what their hearing is

really like, do self-assessments of them and their communication partners, that's the politically correct term for spouses now I think, whatever term you want to use try to dig into this more to find out what's going on. Because we're ready to make some really huge changes with not nearly enough information.

I'd be happy to help with those studies. I've already talked to the student that presented this morning, Chase, wherever you are I'm going to find you. Thank you.

DR. BROCKMAN: Thank you. Reaction to that?

DR. RUCH: I fully agree. And my concern is for the ones who are not able to self-treat and self-diagnose. What's the outlook for -- for these individuals because I believe they will not immediately go and seek proper care?

They will probably just take the device, put it in a drawer which was an issue we faced in the hearing aid industry couple years back as well, but we're down to 3 percent of units in the

drawer.

And if they delay proper care, which is a likelihood potentially that's what they're going to do, what does it mean then do the cost they produce with the comorbidities which can be many fold of a proper treatment in the first place.

DR. BROCKMAN: Thank you. Okay. Two more questions then we're almost out of time.

UNKNOWN SPEAKER: Okay. Okay. I was going to say something else but when I heard Heinz Ruch on this. It is much more likely that somebody who takes an old device and it works out for him start suspecting that he may have a problem and they may actually go and see an MD for this reason.

It is much less likely if they think I don't have a -- just deny it, don't want to try and it's very expensive. They will never see an MD in that case. That's one.

The other thing there's tons of data, tons of data somebody said this on the psychometric analysis. These are very constrained

tests. And people can find their best response much better than an objective procedure.

And this -- we don't need to do studies. From 1950s the studies have been done. As Mead said, ReSound had two different types of devices. Same device fitted by an audiologist and also fitted by an audiologist of the sound positon switch where people actually -- audiologists ask them which one do you prefer. Do you think -- do you know which device has less returns? The one where people had the sound position switch. It was our best product ever. Ever.

So people can do that. And it's not really reasonable to deny, I think.

DR. BROCKMAN: Thank you.

UNKNOWN SPEAKER: Two points. On the children, one, we have the Department of Education as a backstop. If there's a problem, we have children's grades. So that's an unrealistic thing to think because they're over the counter parents are suddenly rushing out and going to harm their children because, hey, we have a cheap solution.

What is causing parents to buy over-the-counter hearing aids is states' tax credits or limits on hearing aid coverage. So when you have a state that only covers hearing aids up to $1,500 and to age 15 like the State of New Jersey, I think it's 1,500 but it's definitely age 15, that's what's causing parents to run out and get cheap hearing aids.

You have early intervention in their earliest years so that's not an issue because that covers hearing aids.

So the misnomer that suddenly parents are harming children is really ridiculous because, first of all, if you have the Department of Education, IEPs, you have testing in schools for hearing, that's just -- that doesn't even make any sense.

As for the older adults and the audiologists you also have problems if you have a lack of quality of care among audiologists that's consistent. So you have some audiologists who are still doing voice audiograms which is ridiculous

because from every time you go to one audiologist to another you get a completely different test depending if the audiologist has a deep voice or a high-pitched voice depending on where your hearing loss is.

So there has to be a much more consistent. And ASHA and all the audiology organizations really need to push for the CD or whatever the current equivalent is to make sure you have consistent testing with a consistent type of testing across the board. Because also what we're seeing on the -- on the handheld devices is an initial testing. You think you have a hearing loss? Do I have a hearing loss? Maybe I should get a -- and it's almost like the entryway.

But yes, we need people to go. And sometimes going to the doctor first is beneficial before going to the audiologist because if you have a lot of excessive hearing wax and you have a hearing test done as my daughter did then if you have to go back to the doctor, costs more money.

And each one of these visits is an expense.

So I think what we really need is a prescribed protocol of how this works. Do you go to the doctor first? Do you go to the audiologist? What does the audiologist do?

And we need to disrupt this model because the old model doesn't work. And a lot of this is very self-preservation of jobs and the lack of focusing on the end user.

And the perfect example here is we have a whole event --

DR. BROCKMAN: I am going to ask you to wrap up.

UNKNOWN SPEAKER: -- one last thing -- a whole event here on hearing loss. No one focused on the hearing -- on the end user of people who wear hearing aids. There is not an assistive listening system in this room.

Initially the captioning was not near the speaker and no one focused on that. So we have a lot of experts with no expert focusing on the end user. And we need to start focusing on the end

user whatever the decisions made are.

DR. BROCKMAN: This is about patients. Thank you. So we are going to take a break.

DR. NANDKUMAR: Yeah. It's a short ten-minute break.

DR. BROCKMAN: Ten-minute break.

DR. NANDKUMAR: We are running a little late so.

DR. BROCKMAN: Back at 4:40.

DR. NANDKUMAR: We'll be back at 4:40.

(Whereupon, a brief recess was taken at 4:30 p.m., and resumed at 4:42 p.m.)

DR. NANDKUMAR: Please take your seats. Okay. We're going to begin Session 3 on the quality standards for manufacturing hearing aids.

The first speaker is going to be Mead Killion from Consumer Technology Association.

DR. KILLION: Good afternoon. My fifth grade teacher searching for some way of saying something nice about me on the report card said, "Mead loves to share his thoughts with others."

I still am there and I'm glad to be

here. I have some background remarks. I believe there are several things we can all agree upon. It is not good for someone with hearing loss to go without amplification.

Millions of persons have benefited enormously from hearing aids. There's a natural aging process that affects everyone fortunate enough to live long enough, including saggy skin and hearing loss. Neither is usually a medical problem which can be cured by a doctor.

Fourth and maybe more important, there are people who could benefit from conventional hearing aids, but can't afford them. 45 million in our country live below the poverty line. One 4 percent of the Hispanic population in Arizona with hearing loss gets hearing aids.

(Brief pause). Why do we need a quality standard? I'm speaking today on behalf of the CTA, the PSAP quality standard. My co-chair -- or I'm her co-chair will be speaking later.

Why do we need a quality standard? Well, because a standard that characterizes good

personal sound amplifiers may provide a starting point for the future.

The first important thing to say is that this is not an FDA standard or an FDA regulation. It is a voluntary standard much like the sticker on your TV set that says close captioning will work on your TV set. It's a Good Housekeeping Seal of Approval.

The task was challenging because existing hearing aid standards describe how to measure hearing aids, but are completely silent on what they should do.

I'm happy to report that the CTA PSA quality standard draft described below is now in the prevote comment period. It has three levels of categories, features.

The first is you measure it. There's a measurement procedure and a value is specified that defines a threshold. For again, maximum distortion.

The second is the measurement is -- procedure is defined and a value is reported. For

example, battery life.

And the third, the presence of a feature is identified further details are opposite. For example, noise reduction.

Level 1 criteria, bandwidth. We chose standard bandwidth above -- greater than or equal to 5 kHz. You -- if you make 10 kHz you can call it wideband.

Frequency response. Smoothness, no response peak beyond 10 DB. Distortion limits for input and output, maximum acoustic output 115 DB sound field equivalent. And that takes a couple moments -- by the NIOSH '98 criteria and that gives you 30 seconds to remove -- turn it off or remove it from your ear before it becomes annoying.

On the other hand, 115 is the equivalent peak of some of the sound level measurements I've made in the first balcony of the Chicago Symphony over 10 or 15 years. And so if you drop it below that you would get clipping on normal music.

Self-generated noise, 30 DBA maximum.

That's equivalent to saying that the aided threshold should be no more than about 10 DBHL and latency of 15 milliseconds.

The Level 2 criteria measurement reported value battery life. That's self-evident.

Level 3, noise reduction. Again, you can say that the hearing aid has that. And, of course, in your literature you may go into more detail. SNR enhancement such as directionality or DSP noise reduction, automatic gain or tone control, feedback control cancellation, personalization or whether the ear is to be open or closed.

In order to permit the use of standard 2cc coupler measurements or ear simulator testing conversion tables are supplied appropriate to each measurement so that anyone with that equipment can check whether it does or doesn't meet the standard.

For example, if the maximum allowable 115 DBA SPL referred to the sound field, if you had at 2500 if you had a 2cc coupler number of 120

that would actually -- if you referred it back to the sound field that would be 115, which it would just about pass.

The bandwidth we -- after lots of debate chose the 500 to 3,000 Hz RMS average, but it's RMS average and the reference. And then the amount that the peak -- third octave peak goes above that is considered the peak height.

The -- did I say peak? I'm sorry. The bandwidth -- well, the bandwidth then is from a line 10 dB below that and it's where it crosses. And so this one has a bandwidth of 160 to 3,500 Hz, which would not pass the requirements.

The response smoothness, it's again the wherever -- why does that -- go back. Wherever the peak occurs you take that point -- that frequency and you go two one-third octaves down, two one-third octaves up, draw the line, and that's your base. And then you see how high the peak is above that.

A few months ago, as reported earlier, the European Association of Hearing Aid

Professionals provided data on 27 personal sound amplifiers on the market in Europe. And one of the papers gave each of the freq- -- gave data on each of them. A very, very careful measurement job.

A quick look at their data showed that none of these devices would pass the proposed CTA PSAP standard requirements which were set before those data become available.

Three criteria were examined as usually enough to knock them out -- bandwidth less than proposed 5 kHz, peak exceeding 10 dB, maximum output exceeding 115 dB refer to the sound field.

So in this particular case we have the -- it failed for peak, it failed for bandwidth -- peak of 135 dB -- and maximum output of 135, sorry. And a peak of some larger number.

So I'll just go quickly through this -- these 27 devices and you'll see all of them failed -- most of them failed for all three reasons.

(Brief pause). I believe all of these slides will be made available later so that I went

quickly.

In contrast to all these devices that fail, there are existing PSAPs in the United States that do pass these tests. For one device, independent research has shown nearly as good -- actually two studies -- nearly as good speech intelligibility performed in quiet and in noise as digital hearing aids individually fitted to NAL-NL2.

And this is the QST Bean. You'll see at the bottom the bandwidth which has to be in an ear simulator if you're going above 8 kHz. And it is from whatever it is, 100 Hz to 16 kHz, peak of 3 dB, maximum output of 110.

Another one which has been discussed favorably by other people today -- I chose it because it was another Chicago company who's an engineer I knew -- Sound World Solutions.

And it has a peak of -- this is the PSAP version. There's an identical version with different software that's the hearing aid. The peak is 3 dB, the bandwidth is 6.3 kHz, and the

maximum output is 113.

What about hearing aids? Well, in the past many hearing aids would have failed these tests, especially bandwidth. But today many state-of-the-art hearing aids do pass. And three that somebody else put on before me from the committee -- the Wildex Dream, the ReSound Linx, the Sivantos Pure Binax.

So our bar, in other words, the set of standards, we felt it was not inappropriately high. Good hearing aids pass it. All of the 27 bad PSAPs didn't pass it.

At the same time there's been a great deal of concern about the quality of PSAPs. It can be higher than that of some hearing aids, some PSAPs.

The next slides give a comparison of actually three digital hearing aids. One popular in 2003, another one 2008, and one introduced in the last couple of years. Presumably the purchasers were told wear it a while and you'll get used to it.

These are live recordings. (Playing music). I turned that -- one more time. (Playing music). What in the world? (Playing music).

And not surprisingly in signal noise ratio tests that degraded the signal noise ration about 4 and a half DB compared to the open ear.

(Indiscernible). A few years ago -- I'm a high-tech guy, right?

A few years ago a friend sent me a hearing aid that was about to go into production. I think he sent it because he was concerned about it and asked if I would do formal -- if we would do formal listening tests, which we said sure we'd do it.

And then when I sent him the results of the listening test assuming that that would kill it I asked him a couple years later what happened. And he said, "Oh, we put it in production."

DR. NANDKUMAR: Mead, we're out of time so can you --

DR. KILLION: What?

DR. NANDKUMAR: We are out of time on

your talk.

DR. KILLION: Are we out?

DR. NANDKUMAR: Yeah.

DR. KILLION: Can I do two more -- one more?

DR. NANDKUMAR: Very quickly.

DR. KILLION: (Plays music). I timed this and I was nine minutes, but I must have gotten excited. Thank you.

DR. NANDKUMAR: Thank you. The next speaker is Dave Fabry of Hearing Industries Association.

DR. FABRY: Thank you. I appreciate the opportunity to address you today. My name is Dave Fabry. I'm the vice president of audiology and professional relations at Starkey Hearing Technologies.

I have a Ph.D. in hearing science from the University of Minnesota, I'm a past president of the American Academy of Audiology, and past chair of audiology at Mayo Clinic in Rochester, Minnesota.

I'm here today, however, on behalf of the Hearing Industries Association. HIA is the association of companies that manufacture hearing aids, accessories, and components. HIA members manufacture more than 90 percent of the hearing aids sold in the United States and spend over $600 million per year on research and development for hearing aids.

HIA of course supports greater access to hearing aids. HIA members supply hearing aids through a wide variety of evolving distribution channels. And has been discussed by Dr. McQuade and others previously today, untreated hearing loss is an important health condition linked with many other medical conditions.

Raising awareness for the importance of hearing and expanding the access to hearing aid technology are both critical, but the PCAST recommendations are the wrong way to accomplish this.

Deregulation would leave the public with no protection from inappropriate, unsafe,

defective or ineffective products. Moreover, PCAST's unsupported assertions regarding innovation and regulation are wrong. As a science-based agency, FDA should give this report little or no weight.

PCAST makes three main flawed and unsupported recommendations. Number one, that basic hearing aids should be sold over the counter; number two, such devices should be subject to minimal or no FDA regulation including no quality system requirements; and number three, that PSAPs should be promoted to treat hearing loss, but without being subject to FDA requirements.

These recommendations are based on three main erroneous assertions. FDA regulation, in particular the QSR, stifles innovation and raises costs unnecessarily, age-related hearing loss can be self-diagnosed and self-treated, and hearing professionals are an unnecessary and costly barrier to access.

PCAST asks that consumers choose between

quality and innovation. HIA members have proven that this is a false choice. Consumers can have both. Companies that care about quality use design controls and other quality systems to maximize manufacturing efficiency and product innovation and to minimize complaints, returns, and recall potential. This lessens cost.

Design controls support innovation by identifying risks and design problems early so we can concentrate resources on the most promising new ideas in technologies. Good documentation allows us to keep what works well and effectively investigate what does not.

This continuous improvement model not only saves money and lessens time to market over the long run, it is the hallmark of ISO global quality standards, not just the QSR.

On top of this compliance with FDA regulations account for only a negligible fraction of total manufacturer revenues as indicated in this slide. As you see, the elimination of QSR would account for a miniscule .06 incremental

percent of revenue taking into account steps that we would need to follow anyway.

If the entire savings from eliminating QSR were passed onto consumers, it would reduce the cost of a $1,000 hearing aid with essential services by approximately 20 cents. Clearly this would have no impact at all on hearing aid affordability.

Put simply, it would be irresponsible for any company to ignore the steps required under QSR regulations when designing and manufacturing hearing aids. These steps do not hinder innovation, do not create excessive burden, and we see no basis for exempting hearing aids sold to Americans from QSR basis or not.

Voluntary industry controls are no substitute for the QSR. Congress gave FDA authority to implement design controls because design defects were causing almost half of all recalls. FDA stated in the QSR preamble in 1996, and I quote, "that adherence to design controls is necessary to protect the public from potentially

harmful devices," end quote, and to ensure that they, quote, "will perform as intended when produced for commercial distribution."

That observation remains true today. As air conduction hearing aids are exempt from 510(k) clearance, FDA would have no tool left to enforce product quality standards if they were exempt from QSR.

The QSR does not dictate how manufacturers design and produce their products. In crafting the QSR FDA was careful not to stifle innovation. This proof that QSR compliance and innovation can coexist comes from the rapid, robust advances made by the devices industry in general and hearing aid manufacturers in particular.

PCAST paints the hearing aid industry as stodgy offering unfashionable beige products and lacking in innovation. However, as FDA knows, hearing aid manufacturers have introduced dramatic advances in recent years. We are consistently at the cutting edge of digital innovation.

For example, contrary to what PCAST noted in its report, 3-D printing technology has been used for decades, years, to make customized ear molds in hearing aids. Directional microphone technology in nearly all models and single microphone noise reduction algorithms already allow noise source identification and cancellation as well as speech localization and recognition via acoustic scene classification.

Modern feedback cancellation algorithms have paved the way for open fit, power, and invisible styles to deliver broadband amplification while minimizing occlusion and largely eliminating feedback.

Nanotechnology provides hydrophobic and oleophobic resistance for hearing aids that live in a hostile work environment, the ear canal.

Bluetooth and similar wireless features are used to stream context directly from smartphones, televisions, music players, and laptops eliminating feedback. Smartphones can also be used to control volume and change programs

for various listening environments.

All this has occurred while hearing aids have been subject to the QSR. QSRs and hearing aid innovation are entirely compatible.

And, yes, hearing aids have already become more fashion forward available in multiple colors and patterns. Maybe not yet quite bling, but getting closer.

PCAST endorsed PSAPs for hearing loss. There should be no question that PSAPs marketed to treat hearing loss are devices. To say otherwise would be to rewrite 40 years of FDA regulation, not to mention the FDC Act.

PCAST suggested that the industry develop its own standards with FDA participation and approval; however, PSAPs as defined by FDA are not devices and therefore are outside FDA's standards setting rule.

Moreover, FDA will have no enforcement authority if PSAPs do not meet these standards. In addition, consumers would have no assurance of compliance with voluntary standards.

As noted by other speakers, PSAPs present both an acute risk in the form of over amplification and a chronic risk in terms of under treatment. FDA should adopt the draft PSAP guidance document as written.

Proponents of PSAPs and OTC hearing aids that enable consumers to eliminate visits to healthcare professionals state without any supporting evidence that this would increase hearing aid usage. This assumption is belied by global data nor is central role -- nor is a central role for the hearing professional a barrier to adoption. Rather it's critical to satisfaction and usage.

The key role of the hearing professional is supported by the high adoption and satisfaction rates of users in countries where the role is central. Conversely, the adoption and satisfaction rates in Japan in South Korea where hearing aids are sold OTC and PSAPs are marketed as hearing solutions are markedly lower.

Japan allows residents to easily

purchase hearing aids without professional examination in a wide variety retail and online outlets. Yet only 13 percent of people with hearing loss adopt them with a 46 percent binaural fitting rate.

Usage is similar in Korea where only 17 percent of people with hearing loss obtain them and 12 percent use them. The U.S. adoption rate is 30 percent and is 72 percent binaural rate providing improved localization, benefit, and outcome. Every access does not mean -- easy access does not mean adoption increases or better outcomes.

A 2015 study found that only 39 percent --

DR. NANDKUMAR: Dave?

DR. FABRY: -- of people in Japan were satisfied with their hearing aids.

DR. NANDKUMAR: You're out of time.

DR. FABRY: Go to -- yeah. Okay. I will conclude there by saying in summary the QSR is not a barrier to innovation. It's an important

regulation to help industry maintain focus on essential quality standards. Voluntary standards cannot possibly replace mandatory regulations primarily because they would be ignored without consequence. Thank you.

DR. NANDKUMAR: Thank you. The next speaker is Poppy Crum for Dolby Laboratories. I would request the speakers to pay attention to the green, yellow, red light on your podium while you're speaking. So that the red light -- the yellow light means you have one minute to go.

DR. CRUM: Am I good? Thank you. Hello. I'm Poppy Crum. I'm head scientist at Dolby Laboratories and a consulting professor at Sanford University.

Prior to joining Dolby Laboratories I was research faculty in the medical school Center for Hearing and Balance at Johns Hopkins University. I have no financial interest in the material covered in this presentation.

So something that many have said today in different ways I would say I think we all

recognize that age-related hearing loss is not a deterministic condition. Rather many conditions combine of sensory neural hearing loss are the amalgamated accumulation of our life's exposure.

Including exposure to loud noise, ototoxic elements such as ototoxic drugs or pathological disease. And changes in the mechanical stiffening of the basilar membrane ordinary behavior of the cochlear peripheral processing.

But fundamentally what this does is it creates a continuum that today we describe as qualitative strata of mild, moderate severe hearing loss.

But nonetheless, underlying that is repr- -- what's the experiential and physiological function that's underlying that is a continuum. And it's a continuum that can begin much earlier than typically discussed in presbycusis conditions. And it can manifest as problems in a multidimensional cognate perceptual space in many ways.

There's much recent literature that I think many of you are aware of from Charlie Lieberman and others showing that we can, you know -- you can have -- you can have completely intact hair cells and selectively damage high -- low spontaneous spiral ganglion fibers which would manifest in a completely normal audiogram, yet difficulty hearing speech and noise.

This is very important because there is such a multitude of conditions that can be affected in facilitating how someone interacts in the world.

So rapid -- combine that with the rapid technological advances in sensory enhancement that have created a conflicting environment between regulation and innovation in the facilitation of helping users who could benefit from current technologies.

So how do we bridge this chasm? How do we bridge the capabilities of consumer grade devices with the -- what we want to do which is effect the user in need.

Three key actions. One, we have to establish device performance standards. So I must -- I have to disclose I'm the other co-chair of the PCAST -- not of -- the other co-chair of the PSAP standardization process that's under -- going -- that we're currently underway with CTA. And Mead Killion is my other co -- is my co-chair.

We also have to increase facilitation of increased hearing health self-monitoring. This is absolutely something that should be commonplace. And we have to recognize that mitigation of mild to moderate hearing loss deficits is inseparable from the personalized signal processing needed for many consumer entertainment and lifestyle devices.

I talk about this a little more, but when we think about something as, you know -- things we care about in my world which are we actually do care about dialog enhancement, loudness leveling. But things like spatialized sound. We all have a personalized head-related transfer function. I can't create a personalized head-related transfer function that's going to

allow you to experience the capabilities of my technologies without also mitigating your hearing loss to some degree.

And our signal pro- -- and the signal processing capabilities of many of these companies that do these types of -- provides these types of experiences are quite sophisticated.

So current regulations prohibiting PSAP developers from making truthful claims about their devices. And one thing I wanted to touch on here is that when we think about PSAPs and what a personal sound amplification product is PSAP is just a name. Amplification is one feature that many PSAPs provide. In my position at Dolby I actually do survey this area very substantially. And, you know, I can't talk about different companies necessarily, but I can tell you the signal processing underlying these devices is not just amplification. There's also sophisticated scene analysis detection, loud -- models of loudness. Many different attributes that are common signal processing tec- -- capabilities and

features you find in hearing aids.

The impact of regulatory recommendations of this innovations is notable. And personalization of many lifestyle experiences beyond communication require device-specific mitigation of hearing deficits.

The real issue for me is -- or for us is if we create products that also provide benefits to those with a hearing deficit, should we not -- shouldn't we be able to describe them that way and allow the user to use the device as it is capable of?

That is a real chasm right now that exists in the market and exists in the device capabilities at a very, very affordable cost price point.

So the empowered health consumer exists today and is everywhere. I -- I -- I cared for two parents who died of cancer. And I will tell you having access to ways of monitoring their system and their physiological state was empowering for them, for myself, but moreover it

informed us, it guided us when we needed to seek a health professional.

Rather than being blind to that information we were guided in ways that were intelligent to when we needed to mitigate something or when we needed to see someone. Notably a higher temperature will prompt solicitation of a medical -- medical advice.

The problem with standardized and accepted self-monitoring of hearing health is notably absent in health conscious consumer. This is despite well understood and scientifically supported psychophysical behavioral methods for controlling and measuring hearing performance. This is a real gap.

I want to use one example that has actually appeared today which is an acoustic neuroma is an examp- -- is a perfect example of why self- monitoring is critical. And we have to change the stigma that exists among the population not just for those of what might be considered an age-related condi- -- threshold, but starting very

young.

I have known five people with acoustic neuromas. And all of them did not self-identify. Introspection is an absolutely terrible way to hope that we get the right answer. You have to give people the tools to self-monitor conditions that they are not particularly good at identifying thresholds for.

In the case of the acoustic neuroma if we actually had self-monitoring you would find people would be more inclined if they would identify that they had a 10 dB, 15 dB unilateral -- unilateral hearing loss and needed to seek a professional care much earlier than you do perceptually just with self-introspection.

Also consistent scientific studies of hearing loss and physiological damage of aggressive nature continued from failure to stimulate the system. The structures down here from David Ryugo's lab at Johns Hopkins have shown -- or I think this is done in Sydney show, you know, changes from a deaf system that innovation

introducing -- reintroducing innovation.

The importance of innovating a declining system is critical to preservation or to refacilitating physiological change.

And what that means for the societal impact of this is that if we do things or we aren't proactive in getting devices -- more devices to the consumers or the users is that you're almost -- you can be accelerating the derivative of decline.

Facilitation, innovation, stimulation is critical to keep the system at a state that's going to prevent or pro- -- reduce the decay of any deficit.

Algorithmic signal processing necessary to mitigate many problems across these devices. High- PSAPs, low-end hearing aids same chips. Those chips have the same algorithms running on them. You are having many different devices really with the exact same underlying technology at the chip level.

And the impact of evidence -- I'm going

to say this really quickly. What we do need is greater use case extensibility of PSAPs to their functional capabilities to help mitigate hearing impairments that can support these needs.

We need to mitigate the impact of failing to do this and failing to provide innovation to the auditory pathway.

The biggest problem right now with the PSAP industry is the heterogeneity that we see across different devices. How do we mitigate? How do we let the consumer help the consumer self-identify the differences between a McLaren and a Peppa the Pig toy, which my one year old might actually prefer. But this is real thing. Right now there are no standards. And this is a very tractable, solvable problem.

I am very active in many standards organizations in drafting international standards. I've taken part now in the CTA with working with Mead Killion and many other contributors.

What we have to get to are two things in the CTA PSAP quality standard. And again this is

self -- this is an elected standard. It would not be -- it's not mandated. But it would be -- the idea would be that this would be a quality standard where if you meet these -- if you meet these specifications you would -- the device would be, say, CTA certified or certified in some way. And that would be something that is providing the consumer critical information.

The two goals have to be to remove performance capacity from the device to consumer description. And this is true for hearing aids. This does not exist well for hearing aids either. The consumer needs to have more access to this information.

A degree --

DR. NANDKUMAR: Poppy, we are out of time.

DR. CRUM: -- of standardized -- I'm almost done. To create a standardized performance threshold target that can be tracked and attained.

We did this. We created three levels of decreasing specification. And just to summarize

those three levels with the lowest -- with the third level being all you have to say is it present or isn't it. Something like that might be noise reduction, the presence of noise reduction or multiband compression. It's up to the consumer to learn more about that.

Now, level two measurement procedures is defined and a value of the performance feature is reported. So that means we define, we specify how it is measured and you have to report that value.

And a level one where not only do you -- we -- you have to provide -- you have to measure something in a specified metric, we also define the range or the threshold level that something must be within or meet.

So examples of that are distortion limits, frequency bandwidth, and obviously maximum output. All of these things would combine to create a more homogenized threshold performance class of PSAPs that would be very empowering and impactful to the consumer.

So finally I will leave this with

standardized performance targets are critical, can help facilitate improved and safe experience for the consumer, and innovation needs to expand and thrive. Allowing true device descriptions of functional performance capabilities and targets will stimulate this type of development. If you build it, they will come. Thank you.

DR. NAKDKUMAR: Thank you. The next speaker is Chris Struck, Acoustical Society of America.

MR. STRUCK: Anyone still awake out there? I had to check. All right.

Good afternoon. Thank you for hanging in there. My name's Christopher Struck. I'm here on behalf of the Acoustical Society of America. I'm the standards director of the Acoustical Society of America. We are an ANSI-accredited standards development organization. I also am the sole proprietor of a consulting firm in San Francisco.

All right. So a couple things to address in my brief time here. Some -- a recap

again. Some of things -- when you're the last speaker, you know, there's going to be some overlap and redundancy. So I prepare -- everyone had to prepare their slides ahead of time.

There has been a significant amount of innovation over the years in the hearing industry. Most notably in the area of signal processing algorithms. I've got a list here of some of the more significant ones -- multiband compression, adaptive signal processing, feedback cancellation, noise reduction, environmental recognition, wireless binaural processing, also in the areas of measurement and evaluation.

I've got a couple of others here. Some innovation that has continued to progress in hearing science in the areas of auditory models of normal and impaired hearing, lost compensation strategies, non-linear fitting algorithms, binaural processing, you know, I mean, the list can go on. This is not even -- I wouldn't even claim this to be a complete list. But I'll -- I'm listing out what's here. Speech intelligibility,

loudness mapping and calculation and so forth as well as subjective evaluation methods.

And I would be remiss if I did not mention that one of the drivers of miniaturization and things like MEMS microphones was, in fact, the hearing industry. And quite a number of these were developed as colla- -- in my recollection they were developed as collaborative research efforts between industry and academia.

So something that hasn't been spoken about are challenges in hearing instrument design. Now, my background is as an engineer. So I'm going to tell you what the problem looks like from an engineer's perspective, someone who wants to design a device be that a PSAP or a hearing aid.

So some of the challenges are small size, low power consumption. It's got to run off this tiny little battery pill. It also has to be small if you want a high fit rate if you want to fit a lot of ears, including people with small canals. It should be programmable if you want to fit people with different kinds of hearing losses.

That also implies some sort of PC interface for the fitting. And you're talking also probably about multiple inputs and multiple analog- to-digital converters. You might want one microphone, two microphones, three microphones, a telecoil, an auxiliary input.

So one of the things that is interesting is that major IC manufacturers are generally not interest in quantities less than about a million. And that's a lot of units.

There are mechanical constraints and also you have a need for transducers -- microphones, receivers, telecoils, that sort of thing. And that's not to mention the signal processing firmware, fitting software, et cetera. And then lastly there's the manufacturing packaging assembly and quality control.

So from an engineer's perspective or from an engineering perspective the hearing instrument, whatever form it ends up taking, is what we call a system solution. That is to say there's a complete package here in order to come

to a solution.

We've got some form of data or information usually in the form of an audiogram that says something about the particular hearing loss. That is used as input to some sort of a fitting system which then converts that information into a form that is usable by the hearing aid in order to fit that person's loss.

Okay. So it's comprised of hardware and software, a hearing aid and a fitting algorithm. And for it to be successful it needs to be -- it needs to have gain and processing that is particular to the individual's hearing loss. Now that's been alluded to before.

So now in my capacity as a standards developer and a standards person let me talk a little bit in the remaining time about hearing instrument standards.

The very beginning of the day you saw an overview of the FDA and FDA regulations and how they fit into the Federal Register and the code here in the United States. So what was implied

there is that it's a very layered and nested configuration where you've got clauses and subparts and sub- subparts and so forth.

Within there is pointed to an actual QC hearing aid test standard. And that is ANSI/ASA S3.22. And, in fact, one of the challenges we have -- this -- I oversee, oh, God, about 80 working groups and we've got about 100 working standards -- active standards. I've got about 500 volunteers. So it's a rather large spread out organization to develop all of these standards.

And I have to say that the group, Group S3, Working Group 48 is one of the most active and involved groups. And the revision cycle is every five years and they've never missed one in the last 20 years as far as I can see.

That standard is always kept up to date. And, in fact, there's usually a lag until it gets updated into the Federal Register. You may have noticed that in some of the slides it was pointing to 2003. I think it's actually pointing to the revision of 2009. But there is actually a

revision of 2014 so you can see the lag there so I'll make you aware of that.

It is an open, voluntary, accredited consensus standard, okay, and it's referenced by the FDA. I already said that.

But there are a number of other standards I'll just make you aware of. There is actually a HADs, hearing assistance device standard, 3.47. There's another standard, 3.42 about testing hearing aids with a speech-like signal, so a more realistic kind of test of its actual performance.

S3.22, the one that's pointed to in the Federal Register, is a QC, a quality control, standard, okay. So if you're not aware of what that means, that means when you stamp out your widgets all of your widgets are tightly controlled and all your widgets are the same. It doesn't mean that your widget necessarily does a particular thing or does a particular thing well, it just means that they're all the same. That is a quality control standard and that was alluded to

in one of the other presentations. There's a difference between performance and quality so I just want to make that clear.

There's also standards outside of my particular realm regarding fitting systems and the programming and interface. And you heard mention of what's going on in the consumer electronics.

So what about a rule for PSAPs relative to hearing aids? There are some challenges for them. Hearing loss is non-linear. Compensation requires some sort of complimentary non-linear amplification compression.

Sorry, Poppy, we grabbed the same picture and you just happened to go before me. So I told you there'd be overlap.

Signal-to-noise ratio and audibility are often made worse with simpler -- simple linear amplification and there are a number of simple devices out there that are simple linear amplifiers unfortunately.

This has been mentioned already, as well, due to acclimatization, amplification for the

impaired listener often requires repeated fine tuning, counseling, repeated visits. However, some studies do seem to indicate that some degree of self- adjustment may be feasible so, you know, there's arguments to be made on both sides of that.

Here's one of the things that sort of concern me is I think it would be nice if someone -- this was mentioned -- had a good PSAP experience and then decided, you know what, I think my particular loss of I've been counseled by my audiologist, I think I need a more sophisticated device. I need something a little bit more sophisticated.

However, human nature is such that if someone has a bad experience with a PSAP or a hearing aid for that matter that's probably going to be the end of the road. They'll be unwilling to upgrade or change or, you know, we say in the industry they end up in the drawer rather than on your ear.

So it does seem to me as an engineer

that a well-designed, inexpensive, and properly PSAP could work well for a given target loss profile, again, if it was designed properly and it might be an excellent entry-level device. It could work that way.

So conclusion here to wrap up. I'll try and address some of those questions that were asked at the beginning. Consensus QC standards do already exist in both hearing aids and HADs and some clauses could be applicable to PSAPs. And I'll just mention again this ongoing effort in CTA to develop a PSAP standard.

All right. Adverse events and complaints --that was in one of the ones -- those typically apply to clinical trials, not to products. I suppose they could also apply to products. But basically complaints are a warranty issue if you're on the consumer side. And I work on both sides so I have to be cognizant of both of these.

So in terms of complaint handling and so forth that sort of depends. In fact, it's not so

much a regulatory issue as it is an enforcement issue. You can have all the regulations you want, but if they're not enforced I don't know where that -- you know, where that leaves one.

And then the other question was, you know, what do we do -- we talk about the original title of the -- of today's workshop was good manufacturing practice and how do we assure testing.

The fact of the matter is there's really, short of auditing and enforcement, there is no way to assure testing. You can have all the regulations you want. This is really it's an enforcement issue.

So device classification, that's a labeling issue. This was also talked about earlier. So as we say a good manufacturing practice is only a suggestion. And that really isn't something that consumers I've ever worked for actually ever check for.

But there are definitions for what different devices are and you could do a

particular definition for PSAP, as well. So that's the end of my talk.

Let's see, there was -- I don't think I have anything here. My only disclosure is I have no -- I have no financial interest in this and there are a lot of paid members of S3, but it's in the notes and you can look that up. It's part of the presentation. So thank you for your time.

DR. NANDKUMAR: Thank you. I'm sorry to announce that it's 5:30 and we have to conclude the workshop. And so we're not going to do the 20 minutes of Q and A for this session.

So I have to give the concluding remarks. And so this concludes today's workshop on Streamlining GMPs for Hearing Aids. Thank you to everyone here -- the hearing impaired consumers, consumer advocacy groups, the hearing healthcare providers and their respective professional societies, and to industry for your participation today.

We would like to thank everyone for their input and we extend a special thank you to

all the public speakers and the invited speakers. We sincerely appreciate all of the points of view that were shared throughout the day here as well as the written comments that you have submitted to the docket for this workshop.

Again, I wanted to remind everyone that the docket for this workshop will continue to remain open until May 19th for anyone who's like to post additional comments for FDA's consideration after today's workshop.

There was some confusion between May 19th and May 6th. May 6th is the deadline for the 2013 draft PSAP guidance document. That's a separate docket. And so the May 19th is the deadline for the workshop docket.

So this workshop has provided an invaluable opportunity for us at the FDA to hear from the key stakeholders on how we can best regulate hearing aids to promote accessibility and affordability.

We will consider all of the opinions presented at this workshop, the PCAST report, as

well as the Institute of Medicine report that is due to come out in June of this year.

All of your input will help us delineate the next best steps to continue fostering innovations of -- innovation of hearing aids in the United States and ultimately benefit the public.

Thank you again for a very informative workshop.

(Whereupon, the proceedings concluded at 5:31 p.m.)

CERTIFICATE OF NOTARY PUBLIC

I, Nathanael Riveness, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was recorded by me and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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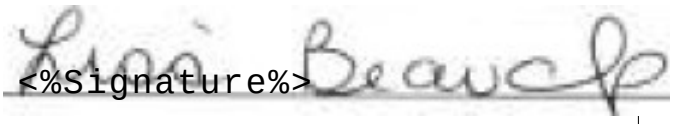
<%Signature%> 

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